ANNEXES

ANNEX 1

Birth defects[1]

[EB126/10 – 3 December 2009]

1. In May 2009 the Executive Board at its 125th session considered an agenda item on birth defects.[2] The Board noted the report on the subject[3] but postponed further discussion to the present session of a draft resolution submitted by China, India and the Republic of Korea. This report is a revised version of the earlier report and reflects comments made by members of the Board. Document EB126/10 Add.1 contains the draft resolution initially considered by the Board and additionally reflects comments and proposals thereon made by members of the Board.

2. This report aims to inform the discussion on birth defects, including definition, epidemiology, burden of disease and interventions for prevention and care, as well as indications of how these interventions might be integrated into existing health services.

DEFINITION

3. The *International statistical classification of diseases and related health problems Tenth Revision* (ICD10), includes birth defects in Chapter XVII "Congenital malformations, deformations and chromosomal abnormalities". Birth defects like inborn errors of metabolism and blood disorders of prenatal origin appear in other chapters. Birth defects can be defined as structural or functional abnormalities, including metabolic disorders, which are present from birth. The term congenital disorder is considered to have the same definition; the two terms are used interchangeably.[4] The eleventh revision of the *International statistical classification of diseases and related health problems* provides an opportunity for a review of the current entry.

4. Irrespective of definition, birth defects can cause spontaneous abortions and stillbirths and are a significant but underrecognized cause of mortality and disability among infants and children under five years of age. They can be life-threatening, result in long-term disability, and negatively impact individuals, families, health-care systems and societies.

BIRTH DEFECTS AND GLOBAL NEWBORN AND CHILD MORTALITY

5. Congenital disorders are a common condition. WHO estimates that some 260 000 deaths worldwide (about 7% of all neonatal deaths) were caused by congenital anomalies in 2004.[5] They are most prominent as a cause of death where overall mortality rates are lower, for example in the WHO European Region, where as many as 25% of neonatal deaths are due to congenital anomalies.

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[1] See resolution EB126.R6.

[2] See document EB125/2009/REC/1, summary record of the second meeting, section 1.

[3] Document EB125/7.

[4] *Management of birth defects and haemoglobin disorders: report of a joint WHO–March of Dimes meeting,* Geneva, Switzerland. May, 2006.

[5] *The global burden of disease: 2004 update.* Geneva, World Health Organization, 2008.

6. Currently, sound estimates do not exist of the number of children who were born with a serious congenital disorder due to genetic or environmental causes. The most common serious congenital disorders are congenital heart defects, neural tube defects and Down syndrome. Haemoglobinophathies (including thalassaemia and sickle cell disease) and glucose-6-phosphate dehydrogenase deficiency, which are not covered by the ICD10 definition of congenital anomalies account for 6% of all congenital disorders.

7. Considerable uncertainties remain as to the incidence and mortality due to congenital disorders, especially in countries which lack adequate registration of deaths. However, these figures indicate that addressing the incidence and mortality associated with congenital anomalies needs to be linked to efforts to achieve the Millennium Development Goal 4 target, of a two thirds reduction in the mortality rate of children under five years of age, between 1990 and 2015.

COMMON CAUSES OF BIRTH DEFECTS

8. Birth defects are a diverse group of disorders of prenatal origin which can be caused by single gene defects, chromosomal disorders, multifactorial inheritance, environmental teratogens and micronutrient deficiencies. Maternal infections such as syphilis and rubella are a significant cause of birth defects in low- and middle-income countries. Maternal illnesses like diabetes mellitus, conditions such as iodine and folic acid deficiency, and exposure to medicinal and recreational drugs including alcohol and tobacco, certain environmental chemicals, and high doses of radiation are other factors that cause birth defects.

PREVENTION

9. The wide range of causes of birth defects means that a portfolio of prevention approaches is needed. Most birth defects of environmental origin can be prevented by public health approaches, including prevention of sexually-transmitted diseases, legislation controlling sound management of toxic chemicals (e.g. certain agricultural chemicals), vaccination against rubella, and fortification of basic foods with micronutrients (iodine and folic acid). Prevention may be considered in terms of life stage (see Appendix).

10. Preconception care aims to ensure the optimal physical and mental well-being of women, and their partners, at the onset of and during early pregnancy, to promote a normal pregnancy and the delivery of a healthy infant. It enables the timely deployment of primary prevention of teratogen-induced birth defects (including those caused by congenital syphilis and rubella), of defects caused by iodine deficiency disorder, of neural tube defects (and possibly other malformations), and of maternal-age-related chromosomal disorders (e.g. Down syndrome). The timely identification of a family risk of inherited disease, and carrier screening with genetic counselling, enable couples to limit family size where there is a known risk.

11. Prevention during pregnancy requires risk identification and management. Some of the interventions and services related to this can raise ethical, legal and social issues and may have cost implications. Such services include prenatal screening and diagnosis for birth defects, selective termination of pregnancy, and the availability of counselling services. Minimally invasive screening methods currently available involve the measurement of several metabolites in the maternal serum. Abnormal levels of biochemical markers are also associated with fetal structural defects such as Down syndrome, neural tube defects and open ventral wall defects. The detection rate of congenital disorders in the first trimester through biochemical screening is improved when it is done in tandem with

ultrasound screening involving nuchal translucency and other ultrasonographical assessments. Ultrasonography in the second trimester is useful to detect major structural defects.

DETECTION, TREATMENT AND CARE

12. Screening of newborn infants for congenital disorders facilitates early detection, treatment and care. Neonatal screening programmes (physical examination of all neonates, screening for congenital hypothyroidism, phenylketonuria, sickle cell disease and glucose-6-phosphate dehydrogenase deficiency) as well as training of primary care providers will support the diagnosis and appropriate referral for treatment of infants with congenital disorders. The physical examination of all newborn infants by trained primary care practitioners is practicable in most health systems and will allow the identification and referral of many birth defects, including cardiovascular defects that are associated with a high risk of early mortality.

13. Treatment of birth defects depends on the level of health care available. It comprises medical therapy, surgery, rehabilitation and palliative care when appropriate.

14. Effective life-saving medical treatment is available for several birth defects, including some common functional single gene defects. Examples include treatment of neonatal jaundice in glucose-6-phosphate dehydrogenase deficiency and with Rhesus incompatibility, congenital hypothyroidism, sickle cell disorders, thalassaemia, haemophilia, cystic fibrosis, and other inborn errors of metabolism. Other treatment options include in utero therapy and postnatal surgical corrections. These are now under research and evaluation in a few selected centres for a number of conditions (e.g. congenital diaphragmatic hernia, congenital heart lesions, myelomeningocele, twin-to-twin transfusion syndrome).

15. Surgery is an important but largely unheralded component of the services required to treat children with birth defects. Over 60% of children with a birth defect have a congenital malformation of a single organ, system or limb. Many birth defects are amenable to cost-effective surgery that can be life saving and improve long-term prognosis. Examples are surgery for simple congenital heart defects, cleft lip and palate, clubfoot, congenital cataracts, and gastrointestinal and urogenital abnormalities.

16. Appropriate treatment is also needed for impairments manifesting themselves after the neonatal period. This includes the early detection and treatment of physical, mental, intellectual or sensory impairments. Access to health and rehabilitation services is important to support the participation and inclusion of affected children.

17. With appropriate training, primary health care practitioners can offer basic care for children with birth defects; recognizing birth defects, diagnosing common problems and identifying associated disabilities. This facilitates basic treatment and counselling at the primary care level, taking into account family and community circumstances and available medical services. Referral to specialist advice is considered when diagnosis is not possible at the primary care level.

IMPLICATIONS FOR SERVICES

18. Services and interventions for the prevention and care of birth defects should be part of existing health-care services, in particular those concerned with maternal and child health. They should combine the best possible patient care with a preventive strategy encompassing education, pre-

conception care, population screening, genetic counselling, and the availability of diagnostic services. That strategy must deliver services for the prevention and care of birth defects as part of a continuum of interventions for maternal and child health. Depending on countries' health-care capacity, the services should go beyond primary health care to include obstetric, paediatric, surgical, laboratory, radiological and, if available, clinical genetic services in secondary and tertiary health care.

19. Effective delivery of services for the prevention and care of birth defects depends on the availability of a range of specialist clinical and diagnostic services, and a primary care system that is able to use them. A nucleus of expertise in medical genetics, paediatric surgery, imaging, and fetal medicine is required, with the potential to expand to meet needs. Conventional laboratory services (haematological, microbiological, biochemical) need to be supplemented with cytogenetic and DNA-based diagnostic services. Introduction may need to be a gradual process. Over time, the new technologies will support more efficient and cost-effective service delivery.

20. The diversity of priority conditions, social structures, cultural conventions and health-care capabilities, means that countries need to be able to consider a range of possible services, assessing costs and relative effectiveness, in order to make a selection and decide the sequence of implementation. However, no organized guidance is yet available on this. The WHO Secretariat has an important potential role to play in identifying successful models, and providing coherent information on community genetics that is accessible to public health policy-makers.

POTENTIAL ACTIONS

21. There are several country-level actions that can support the development of services for the prevention and care of birth defects. Prevention requires basic public health approaches to be integrated into health systems including maternal and child health services. Many of the services and interventions proposed are already within the reach of low- and middle-income countries while others can be added as needs and resources determine.

22. Basic components for a national programme for the prevention and care of birth defects include:

(a) Commitment of policy-makers and provision of adequate managerial support.

(b) A core network of appropriate specialist clinical and laboratory services that can be expanded in response to demand.

(c) Integration of approaches for prevention and care of birth defects into primary health care, with emphasis on maternal and child health.

(d) Education and training for health-care providers, particularly those in primary health care.

(e) Organization of health education programmes for the general population and recognized high-risk groups.

(f) Establishment of effective mechanisms to foster development of patient–parent support organizations, and collaboration with them in caring for people with birth defects and their families.

(g) Definition of the ethical, legal, religious and cultural issues relevant to formulating services appropriate for the local population.

(h) Initiation and monitoring of population-screening programmes such as screening of newborn infants, premarital/pre-pregnancy screening, and screening during pregnancy.

(i) Establishment of appropriate surveillance systems for birth defects.[1]

23. There is a need for technical guidance to establish or to strengthen national programmes for the control of birth defects. The following are priority actions for the international community:

(a) Resolve currently divergent opinions on the health burden of both environmental and constitutional birth defects, using the revision of ICD10 to draw on expert review of available data and to consider broadening the groups of conditions beyond those currently included in the classification of congenital anomalies.

(b) Promote legislation and public health activities to minimize exposure of the population, and particularly of pregnant women, to potentially teratogenic infections, chemicals and other environmental risk factors.

(c) Define effective community services, and support the integration of the prevention and care of birth defects into maternal and child health programmes. Support the provision to ministries of health of an organized assessment of requirements and costs and support in choosing priorities.

(d) Identify successful models that can be applied in low- and middle-income countries.

(e) Facilitate and support international networking on birth defect prevention and care programmes, with emphasis on developing common approaches, and optimizing instruments for information, education, cost analysis and surveillance, among others. Promote informatics approaches in view of their potential to support cost–effectiveness.

ACTION BY THE EXECUTIVE BOARD

24. [In this paragraph, the Board was invited to consider a draft resolution that was adopted at the seventh meeting as resolution EB126.R6.]

[1] Support with this may be obtained by collaboration with existing birth defect surveillance systems including the International Clearinghouse for Birth Defects Surveillance and Research (ICBDSR) which includes ECLAMC (Latin American Collaboration Study of Congenital Malformation), the WHO-supported Craniofacial Anomalies database, and EUROCAT (European Registration of Congenital Anomalies).

APPENDIX

Interventions to prevent or treat birth defects

Preconception care	Pregnancy care	Newborn infant and child care
Family planning • Introducing women to the concept of reproductive choice • Reducing total number of children born with a birth defect • Reducing the proportion of mothers of advanced maternal age, which reduces the birth prevalence of autosomal trisomies, particularly Down syndrome • Allowing women with affected children the option of not having further children **Preconception screening and counselling** • Using family history taken in primary health care to identify individuals at risk of having affected children • Carrier screening for common recessive disorders (thalassaemia and sickle cell disorder) • **Optimize women's diet before and throughout pregnancy** • Promote use of salt fortified with iodine to prevent iodine deficiency disorder • Promote use of a staple food fortified with folic acid and use of supplementary multivitamins with folic acid to prevent neural tube defects and other malformations • Avoid alcohol, tobacco and cocaine • Ensure adequate general diet (protein, calories, iron) **Prevent and treat teratogen-induced infections before and throughout pregnancy** • Syphilis • Rubella (67 countries do not have national rubella immunization programmes) **Optimize pre-conception maternal health and treatment for** • insulin-dependent diabetics • women on treatment for epilepsy • women on treatment with warfarin	**Antenatal screening for** • Rhesus status • Syphilis • Individuals at risk of having children with birth defects using a family history • Down syndrome: advanced maternal age; maternal serum screening; early ultrasound scanning • Neural tube defects with maternal serum screening • Major malformations with ultrasound fetal anomaly scanning (18+ weeks gestation) • Carriers of common recessive disorders (thalassaemia and sickle cell disorder) **Prenatal diagnosis** • Ultrasound • Amniocentesis • Chorionic villus biopsy **Fetal treatment** • For syphilis • Intrauterine transfusion for fetal anaemia Rhesus negativity	**Newborn infant examination** • Trained examiner clinically examining all newborn infants for birth defects **Newborn infant screening** • Congenital hypothyroidism • Phenylketonuria • Cystic fibrosis • Others, as dictated by each country's needs and circumstances **Medical treatment** Examples: • Neonatal jaundice in glucose-6-phosphate dehydrogenase deficiency and Rhesus incompatibility • Treatment and care for children with blood disorders like sickle cell disorder, thalassaemia, etc. • Treatment of some inborn errors of metabolism • Care of children with cystic fibrosis **Surgery** Examples: correction of • simple congenital heart defects • cleft lip and palate • clubfoot • congenital cataracts **Rehabilitation and palliative care** As appropriate

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ANNEX 2

Text of amended Rules of Procedure of the Executive Board[1]

[EB126/26, Annex – 10 December 2009]

CONDUCT OF BUSINESS

Rule 30 bis

The right of reply shall be accorded by the Chairman to any member who requests it. Members should, in exercising this right, attempt to be as brief as possible and preferably deliver their statements at the end of the meeting at which this right is requested.

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VOTING

Rule 47 bis

After the voting has been completed, a member may make a brief statement, consisting solely of an explanation of vote. A sponsor of a proposal shall not speak in explanation of vote thereon, except if it has been amended.

……..

Rule 51 bis

In an election each member, unless he abstains, shall vote for that number of candidates equal to the number of elective places to be filled. Any ballot paper on which there are more or fewer names than there are elective places to be filled shall be null and void.

Rule 51 ter

If during an election one or more elective places cannot be filled by reason of an equal number of votes having been obtained by two or more candidates, a ballot shall be held among such candidates to determine which of them will be elected. This procedure may be repeated if necessary.

[1] See resolution EB126.R8.

ANNEX 3

Confirmation of amendments to the Staff Rules[1]

[EB126/39 – 26 November 2009]

1. Amendments to the Staff Rules made by the Director-General are submitted for confirmation by the Executive Board in accordance with Staff Regulation 12.2.[2]

2. The amendments described in this document reflect decisions expected to be taken by the United Nations General Assembly at its sixty-fourth session on the basis of recommendations made by the International Civil Service Commission in its annual report for 2009.[3] Should the United Nations General Assembly not approve the Commission's recommendations, an addendum to this document will be issued.

3. The financial implications of the amendments for the biennium 2009–2010 include negligible additional costs under the regular budget, which will be met from the appropriate allocations established for each of the WHO regions and for global and interregional activities, and from extrabudgetary sources of funds.

4. The amended Staff Rules are set out [in the Appendix].

AMENDMENTS CONSIDERED NECESSARY IN THE LIGHT OF DECISIONS EXPECTED TO BE TAKEN BY THE UNITED NATIONS GENERAL ASSEMBLY AT ITS SIXTY-FOURTH SESSION ON THE BASIS OF RECOMMENDATIONS OF THE INTERNATIONAL CIVIL SERVICE COMMISSION

Remuneration of staff in the professional and higher categories

5. The Commission recommended to the United Nations General Assembly that the current base/floor salary scale for the professional and higher categories should be increased by 3.04% through the standard consolidation method of increasing base salary and commensurately reducing post adjustment multiplier points (i.e. on a "no loss, no gain" basis) with effect from 1 January 2010.

6. Amendments to Appendix 1 of the Staff Rules have been prepared accordingly and are attached [Appendix].

Salaries of staff in ungraded posts and of the Director-General

7. Subject to the decision of the United Nations General Assembly in respect of the recommendation in paragraph 5 above, the Director-General proposes, in accordance with Staff Regulation 3.1, that the Executive Board should recommend to the Sixty-third World Health Assembly

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[1] See resolutions EB126.R9 and EB126.R10.

[2] *Basic documents,* 47th ed., Geneva, World Health Organization, 2009.

[3] *Report of the International Civil Service Commission for 2009. General Assembly Official Records, Sixty-fourth session, Supplement No. 30* (documents A/64/30, A/64/30 Corr.1 (in French only) and A/64/30 Corr.2).

modifications in the salaries of Assistant Directors-General and Regional Directors. Thus, as from 1 January 2010, the gross salary for Assistant Directors-General and Regional Directors would be US$ 183 022 per annum, and the net salary US$ 131 964 (dependency rate) or US$ 119 499 (single rate).

8. Based on the adjustments to salaries described above, the salary modification to be authorized by the Health Assembly for the Deputy Director-General would entail, as from 1 January 2010, a gross salary of US$ 201 351 per annum with a corresponding net salary of US$ 143 878 (dependency rate) or US$ 129 483 (single rate).

9. The salary adjustments described above would imply similar modifications to the salary of the Director-General. The salary to be authorized by the World Health Assembly, as of 1 January 2010 would therefore be US$ 247 523 per annum gross, US$ 173 890 net (dependency rate) or US$ 154 641 net (single rate).

ACTION BY THE EXECUTIVE BOARD

10. [This paragraph contained two draft resolutions, which were adopted at the ninth meeting as resolutions EB126.R9 and EB126.R10, respectively.]

APPENDIX

Appendix 1 to the Staff Rules

Salary scale for staff in the professional and higher graded categories: annual gross base salaries and net equivalents after application of staff assessment (in US dollars)[1]
(effective 1 January 2010)

STEP

Level	*I*	*II*	*III*	*IV*	*V*	*VI*	*VII*	*VIII*	*IX*	*X*	*XI*	*XII*	*XIII*	*XIV*	*XV*
		*	*	*	*	*									
D-2 Gross	149 903	153 214	156 529	159 846	163 160	166 475									
Net D	110 434	112 589	114 744	116 900	119 054	121 209									
Net S	101 454	103 273	105 085	106 891	108 693	110 485									
					*	*	*	*	*						
P-6/D-1 Gross	137 021	139 804	142 581	145 365	148 149	150 972	153 885	156 794	159 703						
Net D	101 674	103 567	105 455	107 348	109 241	111 132	113 025	114 916	116 807						
Net S	93 979	95 623	97 264	98 900	100 534	102 164	103 787	105 410	107 028						
											*	*	*		
P-5 Gross	113 404	115 771	118 140	120 504	122 874	125 238	127 607	129 974	132 341	134 707	137 075	139 441	141 810		
Net D	85 615	87 224	88 835	90 443	92 054	93 662	95 273	96 882	98 492	100 101	101 711	103 320	104 931		
Net S	79 537	80 967	82 393	83 818	85 241	86 659	88 077	89 491	90 904	92 314	93 721	95 124	96 528		
													*	*	*
P-4 Gross	92 907	95 064	97 221	99 378	101 626	103 909	106 196	108 478	110 763	113 044	115 331	117 612	119 897	122 182	124 468
Net D	71 393	72 946	74 499	76 052	77 606	79 158	80 713	82 265	83 819	85 370	86 925	88 476	90 030	91 584	93 138
Net S	66 482	67 897	69 311	70 720	72 130	73 539	74 946	76 351	77 754	79 157	80 558	81 958	83 357	84 755	86 151
														*	*
P-3 Gross	75 972	77 968	79 967	81 961	83 960	85 956	87 951	89 951	91 947	93 943	95 943	97 936	99 936	102 044	104 157
Net D	59 200	60 637	62 076	63 512	64 951	66 388	67 825	69 265	70 702	72 139	73 579	75 014	76 454	77 890	79 327
Net S	55 259	56 581	57 906	59 227	60 551	61 871	63 192	64 517	65 837	67 159	68 477	69 796	71 112	72 431	73 749
												*			
P-2 Gross	61 919	63 707	65 492	67 279	69 065	70 850	72 638	74 419	76 208	77 996	79 779	81 568			
Net D	49 082	50 369	51 654	52 941	54 227	55 512	56 799	58 082	59 370	60 657	61 941	63 229			
Net S	46 037	47 205	48 368	49 534	50 698	51 864	53 049	54 230	55 417	56 600	57 781	58 967			
P-1 Gross	47 968	49 496	51 146	52 867	54 579	56 296	58 014	59 732	61 444	63 161					
Net D	38 854	40 092	41 325	42 564	43 797	45 033	46 270	47 507	48 740	49 976					
Net S	36 651	37 790	38 927	40 068	41 207	42 344	43 484	44 609	45 728	46 848					

D = Rate applicable to staff members with a dependent spouse or child; S = Rate applicable to staff members with no dependent spouse or child.

* = The normal qualifying period for a within-grade increase between consecutive steps is one year, except at those steps marked with an asterisk, for which a two-year period at the preceding step is required (Staff Rule 550.2).

ANNEX 4

Draft global strategy to reduce the harmful use of alcohol[1]

[EB126/13, Annex 1 – 3 December 2009]

Setting the scene

1. The harmful use of alcohol[2] has a serious effect on public health and is considered to be one of the main risk factors for poor health globally. In the context of this draft strategy, the concept of the harmful use of alcohol[3] is broad and encompasses the drinking that causes detrimental health and social consequences for the drinker, the people around the drinker and society at large, as well as the patterns of drinking that are associated with increased risk of adverse health outcomes. The harmful use of alcohol compromises both individual and social development. It can ruin the lives of individuals, devastate families, and damage the fabric of communities.

2. The harmful use of alcohol is a significant contributor to the global burden of disease and is listed as the third leading risk factor for premature deaths and disabilities in the world.[4] It is estimated that 2.5 million people worldwide died of alcohol-related causes in 2004, including 320 000 young people between 15 and 29 years of age. Harmful use of alcohol was responsible for 3.8% of all deaths in the world in 2004 and 4.5% of the global burden of disease as measured in disability-adjusted life years lost, even when consideration is given to the modest protective effects, especially on coronary heart disease, of low consumption of alcohol for some people aged 40 years or older.

3. Harmful drinking is a major avoidable risk factor for neuropsychiatric disorders and other noncommunicable diseases such as cardiovascular diseases, cirrhosis of the liver and various cancers. For some diseases there is no evidence of a threshold effect in the relationship between the risk and level of alcohol consumption. The harmful use of alcohol is also associated with several infectious diseases like HIV/AIDS, tuberculosis and pneumonia. A significant proportion of the disease burden attributable to harmful drinking arises from unintentional and intentional injuries, including those due to road traffic crashes and violence, and suicides. Fatal injuries attributable to alcohol consumption tend to occur in relatively young people.

4. The degree of risk for harmful use of alcohol varies with age, sex and other biological characteristics of the consumer as well as with the setting and context in which the drinking takes place. Some vulnerable or at-risk groups and individuals have increased susceptibility to the toxic, psychoactive and dependence-producing properties of ethanol. At the same time low risk patterns of

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[1] Revised in the light of comments made by the Executive Board at its 126th session (see document EB126/2010/REC/2, summary record of the eleventh meeting). See resolution EB126.R11.

[2] An alcoholic beverage is a liquid that contains ethanol (ethyl alcohol, commonly called "alcohol") and is intended for drinking. In most countries with a legal definition of "alcoholic beverage" a threshold for content of ethanol by volume in a beverage is set at ≥ 0.5% or 1.0%. The predominant categories of alcoholic beverages are beers, wines and spirits.

[3] The word "harmful" in this strategy refers only to public-health effects of alcohol consumption, without prejudice to religious beliefs and cultural norms in any way.

[4] See document A60/14 Add.1 for a global assessment of public-health problems caused by harmful use of alcohol, and *Global Health Risks: Mortality and burden of disease attributable to selected major risk factors.* Geneva, World Health Organization, 2009.

alcohol consumption at the individual level may not be associated with occurrence or significantly increased probability of negative health and social consequences.

5. A substantial scientific knowledge base exists for policy-makers on the effectiveness and cost–effectiveness of strategies and interventions to prevent and reduce alcohol-related harm.[1] Although much of the evidence comes from high-income countries, the results of meta-analyses and reviews of the available evidence[2] provide sufficient knowledge to inform policy recommendations in terms of comparative effectiveness and cost–effectiveness of selected policy measures. With better awareness, there are increased responses at national, regional and global levels. However, these policy responses are often fragmented and do not always correspond to the magnitude of the impact on health and social development.

Challenges and opportunities

6. The present commitment to reducing the harmful use of alcohol provides a great opportunity for improving health and social well-being and for reducing the existing alcohol-attributable disease burden. However, there are considerable challenges that have to be taken into account in global or national initiatives or programmes. These include the following:

(a) **Increasing global action and international cooperation.** The current relevant health, cultural and market trends worldwide mean that harmful use of alcohol will continue to be a global health issue. These trends should be recognized and appropriate responses implemented at all levels. In this respect, there is a need for global guidance and increased international collaboration to support and complement regional and national actions.

(b) **Ensuring intersectoral action.** The diversity of alcohol-related problems and measures necessary to reduce alcohol-related harm points to the need for comprehensive action across numerous sectors. Policies to reduce the harmful use of alcohol must reach beyond the health sector, and appropriately engage such sectors as development, transport, justice, social welfare, fiscal policy, trade, agriculture, consumer policy, education and employment, as well as civil society and economic operators.

(c) **According appropriate attention.** Preventing and reducing harmful use of alcohol is often given a low priority among decision-makers despite compelling evidence of its serious public health effects. In addition, there is a clear discrepancy between the increasing availability and affordability of alcohol beverages in many developing and low- and middle-income countries and those countries' capability and capacity to meet the additional public health burden that follows. Unless this problem is given the attention it deserves, the spread of harmful drinking practices and norms will continue.

(d) **Balancing different interests.** Production, distribution, marketing and sales of alcohol create employment and generate considerable income for economic operators and tax revenue for governments at different levels. Public health measures to reduce harmful use of alcohol are sometimes judged to be in conflict with other goals like free markets and consumer choice and can be seen as harming economic interests and reducing government revenues. Policy-makers face the challenge of giving an appropriate priority to the promotion and protection of

[1] See document A60/14 for evidence-based strategies and interventions to reduce alcohol-related harm.

[2] See, for example: WHO Technical Report Series, No. 944, 2007 and *Evidence for the effectiveness and cost–effectiveness of interventions to reduce alcohol-related harm.* Copenhagen, World Health Organization Regional Office for Europe, 2009.

population health while taking into account other goals, obligations, including international legal obligations, and interests. It should be noted in this respect that international trade agreements generally recognize the right of countries to take measures to protect human health, provided that these are not applied in a manner which would constitute a means of unjustifiable or arbitrary discrimination or disguised restrictions to trade. In this regard, national, regional and international efforts should take into account the impact of harmful use of alcohol.

(e) **Focusing on equity.** Population-wide rates of drinking of alcoholic beverages are markedly lower in poorer societies than in wealthier ones. However, for a given amount of consumption, poorer populations may experience disproportionately higher levels of alcohol-attributable harm. There is a great need to develop and implement effective policies and programmes that reduce such social disparities both inside a country and between countries. Such policies are also needed in order to generate and disseminate new knowledge about the complex relationship between harmful consumption of alcohol and social and health inequity, particularly among indigenous populations, minority or marginalized groups and in developing countries.

(f) **Considering the "context" in recommending actions.** Much of the published evidence of effectiveness of alcohol-related policy interventions comes from high-income countries, and concerns have been expressed that their effectiveness depends on context and may not be transferrable to other settings. However, many interventions to reduce harmful use of alcohol have been implemented in a wide variety of cultures and settings, and their results are often consistent and in line with the underpinning theories and evidence base accumulated in other similar public health areas. The focus for those developing and implementing policies should be on appropriate tailoring of effective interventions to accommodate local contexts and on appropriate monitoring and evaluation to provide feedback for further action.

(g) **Strengthening information.** Systems for collecting, analysing and disseminating data on alcohol consumption, alcohol-related harm and policy responses have been developed by Member States, the WHO Secretariat, and some other stakeholders. There are still substantial gaps in knowledge and it is important to sharpen the focus on information and knowledge production and dissemination for further developments in this area, especially in developing and low- and middle-income countries. The WHO Global Information System on Alcohol and Health and integrated regional information systems provide the means to monitor better progress made in reducing harmful use of alcohol at the global and regional levels.

Aims and objectives

7. National and local efforts can produce better results when they are supported by regional and global action within agreed policy frames. Thus the purpose of the global strategy is to support and complement public health policies in Member States.

8. The vision behind the global strategy is improved health and social outcomes for individuals, families and communities, with considerably reduced morbidity and mortality due to harmful use of alcohol and their ensuing social consequences. It is envisaged that the global strategy will promote and support local, regional and global actions to prevent and reduce the harmful use of alcohol.

9. The global strategy aims to give guidance for action at all levels; to set priority areas for global action; and to recommend a portfolio of policy options and measures that could be considered for implementation and adjusted as appropriate at the national level, taking into account national circumstances, such as religious and cultural contexts, national public health priorities, as well as resources, capacities and capabilities.

10. The strategy has five objectives:

(a) raised global awareness of the magnitude and nature of the health, social and economic problems caused by harmful use of alcohol, and increased commitment by governments to act to address the harmful use of alcohol;

(b) strengthened knowledge base on the magnitude and determinants of alcohol-related harm and on effective interventions to reduce and prevent such harm;

(c) increased technical support to, and enhanced capacity of, Member States for preventing the harmful use of alcohol and managing alcohol-use disorders and associated health conditions;

(d) strengthened partnerships and better coordination among stakeholders and increased mobilization of resources required for appropriate and concerted action to prevent the harmful use of alcohol;

(e) improved systems for monitoring and surveillance at different levels, and more effective dissemination and application of information for advocacy, policy development and evaluation purposes.

11. The harmful use of alcohol and its related public health problems are influenced by the general level of alcohol consumption in a population, drinking patterns and local contexts. Achieving the five objectives will require global, regional and national actions on the levels, patterns and contexts of alcohol consumption and the wider social determinants of health. Special attention needs to be given to reducing harm to people other than the drinker and to populations that are at particular risk from harmful use of alcohol, such as children, adolescents, women of child-bearing age, pregnant and breastfeeding women, indigenous peoples and other minority groups or groups with low socioeconomic status.

Guiding principles

12. The protection of the health of the population by preventing and reducing the harmful use of alcohol is a public health priority. The following principles will guide the development and implementation of policies at all levels; they reflect the multifaceted determinants of alcohol-related harm and the concerted multisectoral actions required to implement effective interventions.

(a) Public policies and interventions to prevent and reduce alcohol-related harm should be guided and formulated by public health interests and based on clear public health goals and the best available evidence.

(b) Policies should be equitable and sensitive to national, religious and cultural contexts.

(c) All involved parties have the responsibility to act in ways that do not undermine the implementation of public policies and interventions to prevent and reduce harmful use of alcohol.

(d) Public health should be given proper deference in relation to competing interests and approaches that support that direction should be promoted.

(e) Protection of populations at high risk of alcohol-attributable harm and those exposed to the effects of harmful drinking by others should be an integral part of policies addressing the harmful use of alcohol.

(f) Individuals and families affected by the harmful use of alcohol should have access to affordable and effective prevention and care services.

(g) Children, teenagers and adults who choose not to drink alcohol beverages have the right to be supported in their non-drinking behaviour and protected from pressures to drink.

(h) Public policies and interventions to prevent and reduce alcohol-related harm should encompass all alcoholic beverages and surrogate alcohol.[1]

National policies and measures

13. The harmful use of alcohol can be reduced if effective actions are taken by countries to protect their populations. Member States have a primary responsibility for formulating, implementing, monitoring and evaluating public policies to reduce the harmful use of alcohol. Such policies require a wide range of public health-oriented strategies for prevention and treatment. All countries will benefit from having a national strategy and appropriate legal frameworks to reduce harmful use of alcohol, regardless of the level of resources in the country. Depending on the characteristics of policy options and national circumstances, some policy options can be implemented by non-legal frameworks such as guidelines or voluntary restraints. Successful implementation of measures should be assisted by monitoring impact and compliance and establishing and imposing sanctions for non-compliance with adopted laws and regulations.

14. Sustained political commitment, effective coordination, sustainable funding and appropriate engagement of subnational governments as well as from civil society and economic operators are essential for success. Many relevant decision-making authorities should be involved in the formulation and implementation of alcohol policies, such as health ministries, transportation authorities or taxation agencies. Governments need to establish effective and permanent coordination machinery, such as a national alcohol council, comprising senior representatives of many ministries and other partners, in order to ensure a coherent approach to alcohol policies and a proper balance between policy goals in relation to harmful use of alcohol and other public policy goals.

15. Health ministries have a crucial role in bringing together the other ministries and stakeholders needed for effective policy design and implementation. They should also ensure that planning and provision of prevention and treatment strategies and interventions are coordinated with those for other related health conditions with high public health priority such as illicit drug use, mental illness, violence and injuries, cardiovascular diseases, cancer, tuberculosis and HIV/AIDS.

16. The policy options and interventions available for national action can be grouped into 10 recommended target areas, which should be seen as supportive and complementary to each other. These 10 areas are:

(a) leadership, awareness and commitment

(b) health services' response

(c) community action

(d) drink–driving policies and countermeasures

[1] In this strategy "surrogate alcohol" refers to liquids usually containing ethanol and not intended for consumption as beverages, that are consumed orally as substitutes for alcoholic beverages with the objective to producing intoxication or other effects associated with alcohol consumption.

(e) availability of alcohol

(f) marketing of alcoholic beverages

(g) pricing policies

(h) reducing the negative consequences of drinking and alcohol intoxication

(i) reducing the public health impact of illicit alcohol and informally produced alcohol[1]

(j) monitoring and surveillance.

17. The policy options and interventions proposed below for consideration by Member States for each of the 10 recommended target areas are based on current scientific knowledge, available evidence on effectiveness and cost–effectiveness, experience and good practices. Not all the policy options and interventions will be applicable or relevant for all Member States and some may be beyond available resources. As such, the measures should be implemented at the discretion of each Member State depending on national, religious and cultural contexts, national public health priorities, and available resources, and in accordance with constitutional principles and international legal obligations. Policy measures and interventions at the national level will be supported and complemented by global and regional efforts to reduce the harmful use of alcohol.

POLICY OPTIONS AND INTERVENTIONS

Area 1. Leadership, awareness and commitment

18. Sustainable action requires strong leadership and a solid base of awareness and political will and commitment. The commitments should ideally be expressed through adequately funded comprehensive and intersectoral national policies that clarify the contributions, and division of responsibility, of the different partners involved. The policies must be based on available evidence and tailored to local circumstances, with clear objectives, strategies and targets. The policy should be accompanied by a specific action plan and supported by effective and sustainable implementation and evaluation mechanisms. The appropriate engagement of civil society and economic operators is essential.

19. For this area **policy options and interventions** include:

(a) developing or strengthening existing, comprehensive national and subnational strategies, plans of action and activities to reduce the harmful use of alcohol;

(b) establishing or appointing a main institution or agency, as appropriate, to be responsible for following up national policies, strategies and plans;

(c) coordinating alcohol strategies with work in other relevant sectors, including cooperation between different levels of governments, and with other relevant health-sector strategies and plans;

[1] **Informally produced alcohol** means alcoholic beverages produced at home or locally by fermentation and distillation of fruits, grains, vegetables and the like, and often within the context of local cultural practices and traditions. Examples of informally produced alcoholic beverages include sorghum beer, palm wine and spirits produced from sugarcane, grains or other commodities.

(d) ensuring broad access to information and effective education and public awareness programmes among all levels of society about the full range of alcohol-related harm experienced in the country and the need for, and existence of, effective preventive measures;

(e) raising awareness of harm to others and among vulnerable groups caused by drinking, avoiding stigmatization and actively discouraging discrimination against affected groups and individuals.

Area 2. Health services' response

20. Health services are central to tackling harm at the individual level among those with alcohol-use disorders and other health conditions caused by harmful use of alcohol. Health services should provide prevention and treatment interventions to individuals and families at risk of, or affected by, alcohol-use disorders and associated conditions. Another important role of health services and health professionals is to inform societies about the public health and social consequences of harmful use of alcohol, support communities in their efforts to reduce the harmful use of alcohol, and to advocate effective societal responses. Health services should reach out to, mobilize and involve a broad range of players outside the health sector. Health services response should be sufficiently strengthened and funded in a way that is commensurate with the magnitude of the public health problems caused by harmful use of alcohol.

21. For this area **policy options and interventions** include:

(a) increasing capacity of health and social welfare systems to deliver prevention, treatment and care for alcohol-use and alcohol-induced disorders and co-morbid conditions, including support and treatment for affected families and support for mutual help or self-help activities and programmes;

(b) supporting initiatives for screening and brief interventions for hazardous and harmful drinking at primary health care and other settings; such initiatives should include early identification and management of harmful drinking among pregnant women and women of child-bearing age;

(c) improving capacity for prevention of, identification of, and interventions for individuals and families living with fetal alcohol syndrome and a spectrum of associated disorders;

(d) development and effective coordination of integrated and/or linked prevention, treatment and care strategies and services for alcohol-use disorders and co-morbid conditions, including drug-use disorders, depression, suicides, HIV/AIDS and tuberculosis;

(e) securing universal access to health including through enhancing availability, accessibility and affordability of treatment services for groups of low socioeconomic status;

(f) establishing and maintaining a system of registration and monitoring of alcohol-attributable morbidity and mortality, with regular reporting mechanisms;

(g) provision of culturally sensitive health and social services as appropriate.

Area 3. Community action

22. The impact of harmful use of alcohol on communities can trigger and foster local initiatives and solutions to local problems. Communities can be supported and empowered by governments and other

stakeholders to use their local knowledge and expertise in adopting effective approaches to prevent and reduce the harmful use of alcohol by changing collective rather than individual behaviour while being sensitive to cultural norms, beliefs and value systems.

23. For this area **policy options and interventions** include:

(a) supporting rapid assessments in order to identify gaps and priority areas for interventions at the community level;

(b) facilitating increased recognition of alcohol-related harm at the local level and promoting appropriate effective and cost-effective responses to the local determinants of harmful use of alcohol and related problems;

(c) strengthening capacity of local authorities to encourage and coordinate concerted community action by supporting and promoting the development of municipal policies to reduce harmful use of alcohol, as well as their capacity to enhance partnerships and networks of community institutions and nongovernmental organizations;

(d) providing information about effective community-based interventions, and building capacity at community level for their implementation;

(e) mobilizing communities to prevent the selling of alcohol to, and consumption of alcohol by, under-age drinkers, and to develop and support alcohol-free environments, especially for youth and other at-risk groups;

(f) providing community care and support for affected individuals and their families;

(g) developing or supporting community programmes and policies for subpopulations at particular risk, such as young people, unemployed persons and indigenous populations, specific issues like the production and distribution of illicit or informal-alcohol beverages and events at community level such as sporting events and town festivals.

Area 4. Drink–driving policies and countermeasures

24. Driving under the influence of alcohol seriously affects a person's judgment, coordination and other motor functions. Alcohol-impaired driving is a significant public health problem that affects both the drinker and in many cases innocent parties. Strong evidence-based interventions exist for reducing drink–driving. Strategies to reduce harm associated with drink–driving should include deterrent measures that aim to reduce the likelihood that a person will drive under the influence of alcohol, and measures that create a safer driving environment in order to reduce both the likelihood and severity of harm associated with alcohol-influenced crashes.

25. In some countries, the number of traffic-related injuries involving intoxicated pedestrians is substantial and should be a high priority for intervention.

26. For this area **policy options and interventions** include:

(a) introducing and enforcing an upper limit for blood alcohol concentration, with a reduced limit for professional drivers and young or novice drivers;

(b) promoting sobriety check points and random breath-testing;

(c) administrative suspension of driving licences;

(d) graduated licensing for novice drivers with zero-tolerance for drink–driving;

(e) using an ignition interlock, in specific contexts where affordable, to reduce drink-driving incidents;

(f) mandatory driver-education, counselling and, as appropriate, treatment programmes;

(g) encouraging provision of alternative transportation, including public transport until after the closing time for drinking places;

(h) conducting public awareness and information campaigns in support of policy and in order to increase the general deterrence effect;

(i) running carefully planned, high-intensity, well-executed mass media campaigns targeted at specific situations, such as holiday seasons, or audiences such as young people.

Area 5. Availability of alcohol

27. Public health strategies that seek to regulate the commercial or public availability of alcohol through laws, policies, and programmes are important ways to reduce the general level of harmful use of alcohol. Such strategies provide essential measures to prevent easy access to alcohol by vulnerable and high-risk groups. Commercial and public availability of alcohol can have a reciprocal influence on the social availability of alcohol and thus contribute to changing social and cultural norms that promotes harmful use of alcohol. The level of regulation on the availability of alcohol will depend on local circumstances, including social, cultural and economic contexts as well as existing binding international obligations. In some developing and low- and middle-income countries, informal markets are the main source of alcohol and formal controls on sale need to be complemented by actions addressing illicit or informally produced alcohol. Furthermore, restrictions on availability that are too strict may promote the development of a parallel illicit market. Secondary supply of alcohol, for example from parents or friends, needs also to be taken into consideration in measures on the availability of alcohol.

28. For this area **policy options and interventions** include:

(a) establishing, operating and enforcing an appropriate system to regulate production, wholesaling and serving of alcoholic beverages that places reasonable limitations on the distribution of alcohol and the operation of alcohol outlets in accordance with cultural norms, by the following possible measures:

(i) introducing, where appropriate, a licensing system on retail sales, or public health-oriented government monopolies;

(ii) regulating the number and location of on-premise and off-premise alcohol outlets;

(iii) regulating days and hours of retail sales;

(iv) regulating modes of retail sales of alcohol;

(v) regulating retail sales in certain places or during special events;

(b) establishing an appropriate minimum age for purchase or consumption of alcoholic beverages and other policies in order to raise barriers against sales to, and consumption of alcoholic beverages by, adolescents;

(c) adopting policies to prevent sales to intoxicated persons and those below the legal age and considering the introduction of mechanisms for placing liability on sellers and servers in accordance with national legislations;

(d) setting policies regarding drinking in public places or at official public agencies' activities and functions;

(e) adopting policies to reduce and eliminate availability of illicit production, sale and distribution of alcoholic beverages as well as to regulate or control informal alcohol.

Area 6. Marketing[1] of alcoholic beverages

29. Reducing the impact of marketing, particularly on young people and adolescents, is an important consideration in reducing harmful use of alcohol. Alcohol is marketed through increasingly sophisticated advertising and promotion techniques, including linking alcohol brands to sports and cultural activities, sponsorships and product placements, and new marketing techniques such as e-mails, SMS and podcasting, social media and other communication techniques. The transmission of alcohol marketing messages across national borders and jurisdictions on channels such as satellite television and the Internet, and sponsorship of sports and cultural events is emerging as a serious concern in some countries.

30. It is very difficult to target young adult consumers without exposing cohorts of adolescents under the legal age to the same marketing. The exposure of children and young people to appealing marketing is of particular concern, as is the targeting of new markets in developing and low- and middle-income countries with a current low prevalence of alcohol consumption or high abstinence rates. Both the content of alcohol marketing and the amount of exposure of young people to that marketing are crucial issues. A precautionary approach to protecting young people against these marketing techniques should be considered.

31. For this area **policy options and interventions** include:

(a) setting up regulatory or co-regulatory frameworks, preferably with a legislative basis, and supported when appropriate by self-regulatory measures, for alcohol marketing by:

(i) regulating the content and the volume of marketing;

(ii) regulating direct or indirect marketing in certain or all media;

(iii) regulating sponsorship activities that promote alcoholic beverages;

(iv) restricting or banning promotions in connection with activities targeting young people;

[1] Marketing could refer, as appropriate and in accordance with national legislation, to any form of commercial communication or message that is designed to increase, or has the effect of increasing, the recognition, appeal and/or consumption of particular products and services. It could comprise anything that acts to advertise or otherwise promote a product or service.

(v) regulating new forms of alcohol marketing techniques, for instance social media;

(b) development by public agencies or independent bodies of effective systems of surveillance of marketing of alcohol products;

(c) setting up effective administrative and deterrence systems for infringements on marketing restrictions.

Area 7. Pricing policies

32. Consumers, including heavy drinkers and young people, are sensitive to changes in the price of drinks. Pricing policies can be used to reduce underage drinking, to halt progression towards drinking large volumes of alcohol and/or episodes of heavy drinking, and to influence consumers' preferences. Increasing the price of alcoholic beverages is one of the most effective interventions to reduce harmful use of alcohol. A key factor for the success of price-related policies in reducing harmful use of alcohol is an effective and efficient system for taxation matched by adequate tax collection and enforcement.

33. Factors such as consumer preferences and choice, changes in income, alternative sources for alcohol in the country or in neighbouring countries, and the presence or absence of other alcohol policy measures may influence the effectiveness of this policy option. Demand for different beverages may be affected differently. Tax increases can have different impacts on sales, depending on how they affect the price to the consumer. The existence of a substantial illicit market for alcohol complicates policy considerations on taxation in many countries. In such circumstances tax changes must be accompanied by efforts to bring the illicit and informal markets under effective government control. Increased taxation can also meet resistance from consumer groups and economic operators, and taxation policy will benefit from the support of information and awareness-building measures to counter such resistance.

34. For this area **policy options and interventions** include:

(a) establishing a system for specific domestic taxation, on alcohol accompanied by an effective enforcement system, which may take into account, as appropriate, the alcoholic content of the beverage;

(b) regularly reviewing prices in relation to level of inflation and income;

(c) banning or restricting the use of direct and indirect price promotions, discount sales, sales below cost and flat rates for unlimited drinking or other types of volume sales;

(d) establishing minimum prices for alcohol where applicable;

(e) providing price incentives for non-alcoholic beverages;

(f) reducing or stopping subsidies to economic operators in the area of alcohol.

Area 8. Reducing the negative consequences of drinking and alcohol intoxication

35. This target area includes policy options and interventions that focus directly on reducing the harm from alcohol intoxication and drinking without necessarily affecting the underlying alcohol consumption. Current evidence and good practices favour the complementary use of interventions within a broader strategy that prevents or reduces the negative consequences of drinking and alcohol

intoxication. In implementing these approaches, managing the drinking environment or informing consumers, the perception of endorsing or promoting drinking should be avoided.

36. For this area **policy options and interventions** include:

(a) regulating the drinking context in order to minimize violence and disruptive behaviour, including serving alcohol in plastic containers or shatter-proof glass and management of alcohol-related issues at large-scale public events;

(b) enforcing laws against serving to intoxication and legal liability for consequences of harm resulting from intoxication caused by the serving of alcohol;

(c) enacting management policies relating to responsible serving of beverage on premises and training staff in relevant sectors in how better to prevent, identify and manage intoxicated and aggressive drinkers;

(d) reducing the alcoholic strength inside different beverage categories;

(e) providing necessary care or shelter for severely intoxicated people;

(f) providing consumer information about, and labelling alcoholic beverages to indicate, the harm related to alcohol.

Area 9. Reducing the public health impact of illicit alcohol and informally produced alcohol

37. Consumption of illicitly or informally produced alcohol could have additional negative health consequences due to a higher ethanol content and potential contamination with toxic substances, such as methanol. It may also hamper governments' abilities to tax and control legally produced alcohol. Actions to reduce these additional negative effects should be taken according to the prevalence of illicit and/or informal alcohol consumption and the associated harm. Good scientific, technical and institutional capacity should be in place for the planning and implementation of appropriate national, regional and international measures. Good market knowledge and insight into the composition and production of informal or illicit alcohol are also important, coupled with an appropriate legislative framework and active enforcement. These interventions should complement, not replace, other interventions to reduce harmful use of alcohol.

38. Production and sale of informal alcohol are ingrained in many cultures and are often informally controlled. Thus control measures could be different for illicit alcohol and informally produced alcohol and should be combined with awareness raising and community mobilization. Efforts to stimulate alternative sources of income are also important.

39. For this area **policy options and interventions** include:

(a) good quality control with regard to production and distribution of alcoholic beverages;

(b) regulating sales of informally produced alcohol and bringing it into the taxation system;

(c) an efficient control and enforcement system, including tax stamps;

(d) developing or strengthening tracking and tracing systems for illicit alcohol;

(e) ensuring necessary cooperation and exchange of relevant information on combating illicit alcohol among authorities at national and international levels;

(f) issuing relevant public warnings about contaminants and other health threats from informal or illicit alcohol.

Area 10. Monitoring and surveillance

40. Data from monitoring and surveillance create the basis for the success and appropriate delivery of the other nine policy options. Local, national and international monitoring and surveillance are needed in order to monitor the magnitude and trends of alcohol-related harms, to strengthen advocacy, to formulate policies and to assess impact of interventions. Monitoring should also capture the profile of people accessing services and the reason why people most affected are not accessing prevention and treatment services. Data may be available in other sectors, and good systems for coordination, information exchange and collaboration are necessary in order to collect the potentially broad range of information needed to have comprehensive monitoring and surveillance.

41. Development of sustainable national information systems using indicators, definitions and data-collection procedures compatible with WHO's global and regional information systems provides an important basis for effective evaluation of national efforts to reduce harmful use of alcohol and for monitoring trends at subregional, regional and global levels. Systematic continual collection, collation and analysis of data, timely dissemination of information and feedback to policy-makers and other stakeholders should be an integral part of implementation of any policy and intervention to reduce harmful use of alcohol. Collecting, analysing and disseminating information on harmful use of alcohol are resource-intensive activities.

42. For this area **policy options and interventions** include:

(a) establishing effective frameworks for monitoring and surveillance activities including periodic national surveys on alcohol consumption and alcohol-related harm and a plan for exchange and dissemination of information;

(b) establishing or designating an institution or other organizational entity responsible for collecting, collating, analysing and disseminating available data, including publishing national reports;

(c) defining and tracking a common set of indicators of harmful use of alcohol and of policy responses and interventions to prevent and reduce such use;

(d) creating a repository of data at the country level based on internationally agreed indicators and reporting data in the agreed format to WHO and other relevant international organizations;

(e) developing evaluation mechanisms with the collected data in order to determine the impact of policy measures, interventions and programmes put in place to reduce the harmful use of alcohol.

GLOBAL ACTION: KEY ROLES AND COMPONENTS

43. Given the magnitude and the complexity of the problem, concerted global efforts must be in place to support Member States in the challenges they face at the national level. International

coordination and collaboration create the synergies that are needed and provide increased leverage for Member States to implement evidence-based measures.

44. WHO, in cooperation with other organizations in the United Nations system and other international partners will:

(a) provide leadership;

(b) strengthen advocacy;

(c) formulate, in collaboration with Member States, evidence-based policy options;

(d) promote networking and exchange of experience among countries;

(e) strengthen partnerships and resource mobilization;

(f) coordinate monitoring of alcohol-related harm and the progress countries are making to address it.

45. Action by WHO and other international partners to support the implementation of the global strategy will be taken according to their mandates. International nongovernmental organizations, professional associations, research institutions and economic operators in the area of alcohol, all have important roles in enhancing the global action, as follows.

(a) Major partners within the United Nations system and intergovernmental organizations like ILO, UNICEF, WTO, UNDP, UNFPA, UNAIDS, United Nations Office on Drugs and Crime, and the World Bank group will be urged to increase collaboration and cooperation to prevent and reduce harmful use of alcohol, especially in developing and low- and middle-income countries.

(b) Civil society has an important role in warning about the impact of harmful use of alcohol on individuals, families and communities and in bringing additional commitment and resources for reducing alcohol-related harm. Nongovernmental organizations are especially encouraged to form wide networks and action groups to support the implementation of the global strategy.

(c) Research institutions and professional associations play a pivotal role in generating additional evidence for action and disseminating this to health professionals and the wider community. WHO collaborating centres have an important role in supporting the implementation and evaluation of the global strategy.

(d) Economic operators in alcohol production and trade are important players in their role as developers, producers, distributors, marketers and sellers of alcoholic beverages. They are especially encouraged to consider effective ways to prevent and reduce harmful use of alcohol within their core roles mentioned above, including self-regulatory actions and initiatives. They could also contribute by making available data on sales and consumption of alcohol beverages.

(e) The media play an increasingly important role, not only as a conveyer of news and information but also as a channel for commercial communications, and will be encouraged to support the intentions and activities of the global strategy.

Public health advocacy and partnership

46. International public health advocacy and partnership are needed for strengthened commitment and abilities of the governments and all relevant parties at all levels for reducing harmful use of alcohol worldwide.

47. WHO is committed to raising awareness of the public health problems caused by harmful use of alcohol and of the steps that can be taken to prevent and reduce such use in order to save lives and reduce suffering. WHO will engage with other international intergovernmental organizations and, as appropriate, international bodies representing key stakeholders, to ensure that relevant actors can contribute to reducing the harmful use of alcohol.

48. The Secretariat will provide support to Member States by:

(a) raising the awareness of the magnitude of public health problems caused by harmful use of alcohol and advocating for appropriate action at all levels to prevent and reduce such problems;

(b) advocating that attention is given to addressing the harmful use of alcohol in the agendas of relevant international and intergovernmental organizations in order to support policy coherence between health and other sectors at regional and global levels;

(c) promoting and facilitating international coordination, collaboration, partnerships and information exchange to ensure the needed synergies and concerted actions of all relevant parties;

(d) ensuring consistency, scientific soundness and clarity of key messages about preventing and reducing harmful use of alcohol;

(e) promoting intercountry networking and exchange of experiences;

(f) facilitating international networking in order to tackle specific and similar problems (for example, specific problems among indigenous or other minority groups or changing youth drinking cultures);

(g) advocating appropriate consideration by parties in international, regional and bilateral trade negotiations to the need and the ability of national and subnational governments to regulate alcohol distribution, sales and marketing, and thus to manage alcohol-related health and social costs;

(h) ensuring that the WHO Secretariat has processes in place to work with nongovernmental organizations and other civil society groups, taking into consideration any conflicts of interest that some nongovernmental organizations may have;

(i) continuing its dialogue with the private sector on how they best can contribute to the reduction of alcohol-related harm. Appropriate consideration will be given to the commercial interests involved and their possible conflict with public health objectives.

Technical support and capacity building

49. Many Member States need increased capacity and capability to create, enforce and sustain the necessary policy and legal frames and implementation mechanisms. Global action will support national action through the development of sustainable mechanisms and the provision of the necessary

normative guidance and technical tools for effective technical support and capacity building, with particular focus on developing and low- and middle-income countries. Such actions must be in accordance with the national contexts, needs and priorities. Development of the necessary infrastructure for effective policy responses in countries with higher or increasing alcohol-attributable burden is an important prerequisite for attaining broader public health and developmental objectives.

50. WHO is committed to cooperate with other relevant actors at regional and global levels in order to provide technical guidance and support for strengthening institutional capacity to respond to public health problems caused by harmful use of alcohol. WHO will especially focus on support and building capacity in developing and low- and middle-income countries.

51. The Secretariat will provide support to Member States by:

(a) documenting and disseminating good models of health-service responses to alcohol-related problems;

(b) documenting and disseminating best practices and models of responses to alcohol-related problems in different sectors;

(c) drawing on expertise in other areas like road safety, taxation and justice with public health expertise in order to design effective models to prevent and reduce alcohol-related harm;

(d) providing normative guidance on effective and cost-effective prevention and treatment interventions in different settings;

(e) developing and strengthening global, regional and intercountry networks in order to help in sharing best practices and facilitating capacity building;

(f) responding to Member States' requests for support of their efforts to build the capacity to understand the implications of international trade and trade agreements for health.

Production and dissemination of knowledge

52. Important areas for global action will be monitoring trends in alcohol consumption, alcohol-attributable harm and the societal responses, analysing this information and facilitating timely dissemination. Available knowledge on the magnitude of harmful use of alcohol, and effectiveness and cost–effectiveness of preventive and treatment interventions should be further consolidated and expanded systematically at the global level, especially information on epidemiology of alcohol use and alcohol-related harm, impact of harmful use of alcohol on economic and social development and the spread of infectious diseases in developing and low- and middle-income countries.

53. The Global Information System on Alcohol and Health and its regional components were developed by WHO for dynamic presentation of the data on levels and patterns of alcohol consumption, alcohol-attributable health and social consequences and policy responses at all levels. Improving the global and regional data on alcohol and health requires development of national monitoring systems, regular reporting of data by designated focal points to WHO and strengthening the relevant surveillance activities.

54. WHO is committed to working with the relevant partners to shape the international research agenda on alcohol and health, build capacity for research and promote and support international research networks and projects to generate and disseminate data to inform policy and programme development.

55. The Secretariat will provide support to Member States by:

(a) providing an international clearinghouse for information on effective and cost-effective interventions to reduce harmful use of alcohol including promoting and facilitating exchange of information about effective treatment services;

(b) strengthening the Global Information System on Alcohol and Health and the comparative risk assessment of the alcohol-attributable disease burden;

(c) developing or refining appropriate data-collection mechanisms, based on comparable data and agreed indicators and definitions, in order to facilitate data collection, collation, analysis and dissemination at the global, regional and national levels;

(d) facilitating regional and global networks to support and complement national efforts, with a focus on knowledge production and information exchange;

(e) continuing its collaboration with international networks of scientists and health experts to promote research on various aspects of harmful use of alcohol;

(f) facilitating comparative effectiveness studies of different policy measures implemented in different cultural and developmental contexts;

(g) facilitating operational research to expand effective interventions and research on the relationship between harmful use of alcohol and social and health inequities.

Resource mobilization

56. The magnitude of alcohol-attributable disease and social burden is in sharp contradiction with the resources available at all levels to reduce harmful use of alcohol. Global development initiatives must take into account that developing and low- and middle-income countries need technical support – through aid and expertise – to establish and strengthen national policies and plans for the prevention of harmful use of alcohol and develop appropriate infrastructures, including those in health-care systems. Development agencies could consider reducing harmful use of alcohol as a priority area in developing and low- and middle-income countries with a high burden of disease attributable to harmful use of alcohol. Official development assistance provides opportunities to build sustainable institutional capacity in this area in developing and low- and middle-income countries, as do mechanisms for collaboration between developing countries. In that regard, Member States are urged to support each other in the implementation of the global strategy through international cooperation and financial assistance including official development assistance for developing countries.

57. WHO is committed to assist countries upon request in resource mobilization and pooling of available resources to support global and national action to reduce harmful use of alcohol in identified priority areas.

58. The Secretariat will provide support to Member States by:

(a) promoting exchange of experience and good practice in financing policies and interventions to reduce harmful use of alcohol;

(b) exploring new or innovative ways and means to secure adequate funding for implementation of the global strategy;

(c) collaborating with international partners, intergovernmental partners and donors to mobilize necessary resources to support developing and low- and middle-income countries in their efforts to reduce harmful use of alcohol.

IMPLEMENTING THE STRATEGY

59. Successful implementation of the strategy will require concerted action by Member States, effective global governance and appropriate engagement of all relevant stakeholders. All actions listed in the strategy are proposed to support the achievement of the five objectives.

60. The Secretariat will report regularly on the global burden of alcohol-related harm, make evidence-based recommendations, and advocate action at all levels to prevent and reduce harmful use of alcohol. It will collaborate with other intergovernmental organizations and, as appropriate, other international bodies representing key stakeholders to ensure that action to reduce harmful use of alcohol receives appropriate priority and resources.

Links and interfaces with other strategies, plans and programmes

61. This global strategy builds upon regional initiatives such as the Framework for alcohol policy in the WHO European Region (resolution EUR/RC55/R1), the Regional strategy to reduce alcohol-related harm in the Western Pacific Region (resolution WPR/RC57.R5), Alcohol consumption control – policy options in the South-East Asia Region (resolution SEA/RC59/R8), Public health problems of alcohol consumption in the Eastern Mediterranean Region (resolution EM/RC53/R.5) and Actions to reduce the harmful use of alcohol in the African Region (document AFR/RC58/3).

62. Harmful use of alcohol is one of the four main risk factors highlighted in the action plan for the global strategy for the prevention and control of noncommunicable diseases (resolution WHA61.14). The strategy to reduce harmful use of alcohol builds on and links to the other risk factors for noncommunicable diseases and the disease-specific programmes, especially through the global strategy on diet, physical activity and health (resolution WHA57.17), tobacco control (resolution WHA56.1), health promotion and healthy lifestyle (resolution WHA57.16) and cancer prevention and control (resolution WHA58.22).

63. The strategy also links and aligns itself with other related activities in WHO, especially the Mental Health Gap Action Programme, including suicide prevention and management of other substance use disorders as well as programmatic activities on violence and health (resolution WHA56.24), road safety and health (resolution WHA57.10), child and adolescent health and development (resolution WHA56.21) and reproductive health (resolution WHA57.12).

64. With emerging evidence, greater attention is being given to the links between harmful use of alcohol and some infectious diseases and between harmful drinking and development. The strategy also links in with WHO's existing progammes on HIV/AIDS and tuberculosis and its work on reducing health inequities through action on the social determinants of health (resolution WHA62.14) and achieving the health-related development goals including those contained in the United Nations Millennium Declaration (resolution WHA58.30).

65. The implementation of a global strategy to reduce harmful use of alcohol provides a supportive framework for the WHO regional offices to formulate, revisit and implement region-specific policies and, together with the country offices, provide technical support to Member States. Emphasis will also be put on coordination within the Secretariat so that all actions relevant to harmful use of alcohol are in line with this strategy.

Monitoring progress and reporting mechanisms

66. For monitoring progress, the strategy requires appropriate mechanisms at different levels for assessment, reporting and re-programming. A framework with an impact-focused perspective is needed for assessing achievement of the strategy's objectives.

67. WHO's Global Survey on Alcohol and Health and the Global Information System on Alcohol and Health will be important parts of the reporting and monitoring mechanisms. The data-collecting tools of the latter will be adjusted to include the relevant reporting on the process and outcomes of implementation of the strategy at the national level.

68. Regular meetings of global and regional networks of national counterparts offer a mechanism for technical discussion of the implementation of the global strategy at different levels. In addition to taking stock of the process, these meetings could include detailed discussions of priority areas and topics relevant to implementation.

69. Reporting on the implementation of the global strategy to Member States will take place through regular reports to WHO regional committees and the Health Assembly. Information about implementation and progress should also be presented at regional or international forums and appropriate intergovernmental meetings.

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ANNEX 5

Nongovernmental organizations admitted into, or maintained in, official relations with WHO by virtue of, respectively, resolution EB126.R17 and decision EB126(5)

[EB126/28, Annex – 22 January 2010]

African Medical and Research Foundation[1]
Aga Khan Foundation[1]
Association of the Institutes and Schools of Tropical Medicine in Europe
CMC – Churches' Action for Health[1]
Caritas Internationalis
Collegium Internationale Neuro-Psychopharmacologicum
Consumers International[1]
Council for International Organizations of Medical Sciences[1]
Council on Health Research for Development[1]
CropLife International[2]
EuroSafe – European Association for Injury Prevention and Safety Promotion[1]
FDI World Dental Federation[2]
Framework Convention Alliance on Tobacco Control[1]
Global Forum for Health Research[1]
Global Health Council, Inc.[1]
Helen Keller International[2]
International Agency for the Prevention of Blindness[2]
International Alliance of Patients' Organizations[1]
International Association for Biologicals[1]
International Association for Dental Research[2]
International Association of Biologists Technicians[1]
International Association of Cancer Registries[1]
International Association of Hydatid Disease
International Association of Logopedics and Phoniatrics
International Association of Medical Regulatory Authorities
International Catholic Committee of Nurses and Medico-Social Assistants[1]
International College of Surgeons[1]
International Commission on Radiological Protection[2]
International Committee for Monitoring Assisted Reproductive Technologies
International Conference of Deans of French-Language Faculties of Medicines[1]
International Council for Standardization in Haematology[1]
International Council of Nurses[1]
International Diabetes Federation[2]
International Epidemiological Association[1]
International Federation for Medical and Biological Engineering[1]
International Federation of Biomedical Laboratory Science
International Federation of Clinical Chemistry and Laboratory Medicine

[1] Activities concern the period 2007–2009.

[2] Activities concern the period 2006–2008.

International Federation of Fertility Societies[1]
International Federation of Health Records Organizations[1]
International Federation of Hospital Engineering[1]
International Federation of Medical Students' Associations[1]
International Federation of Oto-Rhino-Laryngological Societies[2]
International Federation of Pharmaceutical Manufacturers and Associations[1]
International Federation of Surgical Colleges[1]
International Hospital Federation[1]
International Insulin Federation
International League Against Epilepsy[3]
International Leprosy Association[2]
International Life Saving Federation
International Medical Informatics Association[1]
International Medical Parliamentarians Organization[1]
International Network for Cancer Treatment and Research
International Network on Children's Health Environment and Safety[2]
International Organization against Trachoma
International Organization for Standardization[1]
International Pharmaceutical Federation[1]
International Physicians for the Prevention of Nuclear War[3]
International Society for Burn Injuries[1]
International Society for Telemedicine & eHealth
International Society of Blood Transfusion[1]
International Society of Orthopaedic Surgery and Traumatology[1]
International Society of Radiology[1]
International Society on Thrombosis and Haemostasis[1]
International Solid Waste Association[2]
International Union against Tuberculosis and Lung Disease[2]
International Union for Conservation of Nature and Natural Resources
International Union of Architects[1]
International Union of Basic and Clinical Pharmacology[1]
International Union of Immunological Societies[2]
International Union of Microbiological Societies
International Union of Psychological Science[3]
International Union of Toxicology[2]
Medicus Mundi International – International Organisation for Cooperation in Health Care[1]
OXFAM[1]
Project ORBIS International, Inc. (ORBIS International)[2]
Stichting Global Network of People Living with HIV/AIDS (GNP+)
The Commonwealth Pharmacists Association[1,4]
The International League of Dermatological Societies[1]
The International Pharmaceutical Students' Federation[1]
The International Society for Quality in Health Care Incorporated[1]
The International Society of Radiographers and Radiological Technologists[1]

[1] Activities concern the period 2007–2009.

[2] Activities concern the period 2006–2008.

[3] Activities concern the period 2005–2007.

[4] Previously known as the Commonwealth Pharmaceutical Association.

The Network: Towards Unity For Health[1]
The Save the Children Fund[1]
The Transplantation Society[1]
The World Federation of Acupuncture-Moxibustion Societies[1]
The World Medical Association, Inc.[1]
World Association of Societies of Pathology and Laboratory Medicine[1]
World Blind Union[2]
World Federation for Medical Education[1]
World Federation of Chiropractic[1]
World Federation of Hydrotherapy and Climatotherapy[2]
World Federation of Public Health Associations[1]
World Federation of Societies of Anaesthesiologists[1]
World Federation of Ultrasound in Medicine and Biology[1]
World Organization of Family Doctors[1]
World Self-Medication Industry[1]
World Vision International[1]

[1] Activities concern the period 2007–2009.

[2] Activities concern the period 2006–2008.

ANNEX 6

Guidelines for the WHO review of psychoactive substances for international control[1]

[EB126/21, Annex – 17 December 2009]

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[1] See document EB126/2010/REC/2, summary record of the twelfth meeting, for approval of these guidelines.

I. MANDATE

1. The World Health Organization (WHO) is the specialized agency of the United Nations that conducts the medical, scientific and public health evaluation of psychoactive substances under the Single Convention on Narcotic Drugs, 1961 (the 1961 Convention), as amended by the 1972 Protocol, and the Convention on Psychotropic Substances, 1971 (the 1971 Convention).[1] The guidance document for this evaluation has been developed pursuant to resolutions of the World Health Assembly[2] and of the United Nations Commission on Narcotic Drugs (CND). This document amends the previous version of these guidelines and sets out guidelines establishing the underlying principles of the review procedure, working arrangements within the Secretariat and with external bodies, and the nature of the documentation to be prepared. The guidelines cover WHO's responsibilities under Article 3 of the 1961 Convention and Article 2 of the 1971 Convention concerning whether or not to recommend international control of substances, as well as the assessment of exempted preparations under Article 3 of the 1971 Convention. Common terms and abbreviations are listed in Section VII.

2. The Thirty-third World Health Assembly, by resolution WHA33.27 (1980), requested the Director-General "to promote the initiation and strengthening of national and international programmes for the assessment, scheduling, control and appropriate use of narcotic and psychotropic substances including those of plant origin, and to support such programmes by the development of appropriate guidelines", and further "to strengthen the coordination between the WHO programmes relating to narcotic and psychotropic substances, those dealing with drug policy and management, and other related programmes, and to strengthen collaboration with interested nongovernmental organizations".

3. In the light of experience gained over later years, and following the guidance of the Executive Board,[3] WHO first developed the guidelines document for the evaluation and assessment of narcotic and psychotropic substances for decisions on international control in consultation with CND in 1986,[4] which document was revised in 1990.[5] Amendments and decisions subsequently adopted by the Executive Board in 1994[6] and 1999[7] resulted in a further revision in 2000. Subsequently, at the request of the Expert Committee on Drug Dependence (Expert Committee), supplementary guidelines were submitted to the Executive Board in order to clarify certain issues.[8] The Board considered the proposed supplementary guidelines in May 2004[9] and January 2005[10] when it requested the Secretariat and the Expert Committee to continue their work on the issue. This revision of the guidelines has been prepared in response to that request.

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[1] See Appendix 1 for the most relevant excerpts from these conventions.

[2] Resolution WHA33.27.

[3] Resolution EB73.R11.

[4] Decision EB77(3).

[5] Decision EB85(10).

[6] Decision EB93(16).

[7] Decision EB103(5).

[8] Documents EB114/7 and EB115/12.

[9] Document EB114/2004/REC/1, summary record of the third meeting.

[10] Document EB115/2005/REC/2, summary record of the sixth meeting.

II. UNDERLYING PRINCIPLES

4. The Preamble of the Single Convention on Narcotic Drugs, 1961 provides:

> *"The Parties,*
> Concerned *with the health and welfare of mankind,*
> Recognizing *that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,*
> Recognizing *that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,*
> Conscious *of their duty to prevent and combat this evil,*
> Considering *that effective measures against abuse of narcotic drugs require coordinated and universal action,*
> Understanding *that such universal action calls for international cooperation guided by the same principles and aimed at common objectives,*
> Acknowledging *the competence of the United Nations in the field of narcotics control and desirous that the international organs concerned should be within the framework of that Organization,*
> Desiring *to conclude a generally acceptable international convention replacing existing treaties on narcotic drugs, limiting such drugs to medical and scientific use, and providing for continuous international cooperation and control for the achievement of such aims and objectives ..."*

The Preamble of the Convention on Psychotropic Substances, 1971 provides:

> *"The Parties,*
> Being concerned *with the health and welfare of mankind,*
> Noting *with concern the public health and social problems resulting from the abuse of* certain psychotropic substances,
> Determined *to prevent and combat abuse of such substances and the illicit traffic to which it gives rise,*
> Considering *that rigorous measures are necessary to restrict the use of such substances to legitimate purposes,*
> Recognizing *that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted,*
> Believing *that effective measures against abuse of such substances require coordination and universal action,*
> Acknowledging *the competence of the United Nations in the field of control of psychotropic substances and desirous that the international organs concerned should be within the framework of that Organization,*
> Recognizing *that an international convention is necessary to achieve these purposes ...*"

The WHO review procedure, grounded in considerations of public health and with an evidence-based approach, will utilize the best available relevant information. Consistent with the requirements of the 1961 and 1971 Conventions, WHO will develop scheduling recommendations guided by the provisions in the Conventions regarding the changes in the scope of control of substances and also taking into account the preambles of the Conventions, the need to reduce the risk to public health, including the risk of abuse and ensuring medical availability, and the relevant resolutions of its governing bodies. The Conventions are legal instruments; the WHO review procedure shall be applied in a manner consistent with the letter and the spirit of the Conventions.

III. PROVISIONS OF THE CONVENTIONS

5. The 1961 and 1971 Conventions entrust WHO with the responsibility of reviewing and assessing substances to determine whether they should be controlled under the Conventions. A request for such a review can be initiated by a notification to the Secretary-General of the United Nations by a Party to the Conventions, or by WHO itself.[1] WHO will forward the results of this review to CND which has the responsibility to decide whether to schedule substances under the provisions of the Conventions.[2]

6. The basis for the scheduling recommendation made by WHO is an evaluation of whether specific criteria set forth in the Conventions have been met. Under the provisions of the 1961 Convention, the CND must accept or refuse the WHO recommendation as a whole, except that it may decide to place a substance only in Schedule I and not in Schedule IV if WHO has recommended simultaneous inclusion in both schedules. The CND should in principle accept the medical, scientific, chemical and pharmacological findings of WHO, and when the CND rejects a recommendation, it should be guided by other considerations such as those of an administrative or social nature.[3] In the case of the 1971 Convention, the CND may accept a WHO proposal, but it may also decide to place a substance in a schedule other than that recommended by WHO. With respect to control under the 1971 Convention, WHO's assessment is determinative for scientific and medical matters, but CND may also take into account legal, administrative, economic, social and other factors in reaching its decision.[4] 1971 Convention, Art. 2, para. 5; See also, Commentary on the Convention of Psychotropic Substances (1971 Convention), para. 20 (p. 71). Under the provisions of both Conventions, a Party which disagrees with CND's decision may request a review of such a decision by the Economic and Social Council; the Council may confirm, alter or reverse CND's decision.

7. Under the provisions of Article 3 of the 1971 Convention, a Party may exempt from specific control measures a preparation containing one or more psychotropic substances if the preparation is compounded in such a way that it presents no, or a negligible, risk of abuse, and the substance cannot be recovered by a readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem. A party shall notify the Secretary-General of the United Nations who in turn shall transmit the notification to other Parties, to WHO and to the International Narcotics Control Board. If a Party or WHO has information which it believes requires that the exemption of a preparation should be terminated, it should notify the Secretary-General of the United Nations accordingly and submit information in support of that notification. WHO reviews the data submitted by the Parties that wish to avail themselves of this provision for exemption under the 1971 Convention by applying specific guidelines that have been approved by CND.[5]

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[1] The Director-General represents WHO for the purpose of receiving notifications under the international drug control conventions and of making recommendations concerning the international control of psychoactive substances under those conventions on the basis of recommendations and advice provided to him or her as described in these guidelines.

[2] The scheduling process is defined in Article 3 of the 1961 Convention and Articles 2 and 17 (para. 2) of the 1971 Convention. The scheduling process is described in detail in the commentaries on these Conventions, published by the United Nations.

[3] Commentary on the 1961 Single Convention on Narcotic Drugs (1961 Convention), para. 16–18 (p. 90).

[4] 1971 Convention, Art. 2, para. 5; See also, Commentary on the Convention of Psychotropic Substances (1971 Convention), para. 20 (p. 71).

[5] The specific WHO procedure for review of exempted preparations was developed in accordance with the Commission's guidelines for exemption. These guidelines, which were largely based on recommendations made by WHO, were approved by CND at its Eighth special session and are set forth in its resolution 1 (S-VIII). See the report of the Commission in Economic and Social Council, Official Records, 1984, Supplement No. 3 (Document E/CN.7/1984/13).

8. Under the provisions of the 1961 Convention, preparations of narcotic drugs exempted from specific control measures are listed in Schedule III. New exemptions can be made only by including a preparation in Schedule III, and relevant proposals are reviewed by WHO in the same way as those for single substances.

9. The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (the 1988 Convention), entered into force in November 1990. Article 12 of the 1988 Convention places under international control substances frequently used in the illicit manufacture of narcotic drugs or psychotropic substances. These substances are listed in Table I and Table II of the 1988 Convention. WHO has no formal role to play in the scheduling of such substances under the 1988 Convention. However, it is possible that the same substance may be considered for control simultaneously under the 1961 Convention, the 1971 Convention, or the 1988 Convention. Guidance on how to address such a situation is provided below under the subsection *Assessment for scheduling by the Expert Committee*.

IV. WHO REVIEW PROCEDURE[1]

10. The purpose of the WHO review procedure is to evaluate substances for international control. Using data provided by the Secretariat, the Expert Committee conducts pre-reviews and critical reviews in order to provide scheduling advice to the Director-General.

11. The review of exempted preparations notified by a Party involves a preliminary review by the Secretariat and an evaluation by the Expert Committee.

12. The time schedule for the review procedure should be set by the Secretariat bearing in mind the calendar of CND and its procedural requirements.

Information collection

13. The Secretariat should routinely collect relevant data related to psychoactive substances that are being abused or might have abuse potential and substances convertible into such substances from the literature, WHO programmes, WHO collaborating centres, national health and drug control authorities, intergovernmental and nongovernmental organizations, research and academic institutions and other competent sources.

Pre-review

14. The purpose of the pre-review is to determine whether current information justifies an Expert Committee critical review.

15. A pre-review is initiated when a proposal has been submitted to the Expert Committee with supporting information either by (1) the Secretariat, (2) any member of the Expert Committee, or (3) representatives of other organizations invited to participate in the Expert Committee meeting in accordance with paragraph 35. The Secretariat will put the proposed pre-review of a substance on the agenda of the first possible Expert Committee meeting.

[1] See Appendix 3 for a flow chart of the evaluation procedure.

16. The categories of information for evaluating substances in pre-reviews are identical to those used in critical reviews. The Secretariat shall supply the supporting information required for pre-review in the form of a brief summary of relevant information. At this stage the Expert Committee must decide whether the information warrants a critical review. If the Expert Committee determines that a critical review is not warranted then the Expert Committee should recommend no further evaluation of the substance. The pre-review is a preliminary analysis and findings at this stage should not determine whether the control status of a substance should be changed. The confidentiality of information received by WHO for use in the review will be respected if so requested by the provider. Appropriate arrangements to sustain confidentiality will be made when the Expert Committee has access to the information used to prepare the pre-review.

17. The Expert Committee shall recommend a critical review if it finds that information may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions, using the criteria in paragraphs 48 to 59.

Critical review

18. The purpose of the critical review is to consider whether the Expert Committee should advise the Director-General to recommend the scheduling of, or amending of the scheduling status of, a substance.

19. A critical review is initiated when:

(1) there has been notification from a Party to the 1961 or the 1971 Convention concerning the scheduling of a substance;

(2) there has been an explicit request from CND to review a substance;

(3) pre-review of a substance has resulted in an Expert Committee recommendation for critical review; or

(4) information is brought to WHO's attention that a substance is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any Party.

In respect of case (4), if therapeutic use of the substance is confirmed subsequently by any Party the substance shall be subjected to a pre-review.

Critical review documents

20. The purpose of the critical review document is to provide comprehensive data for use by the Expert Committee in assessing individual substances.

21. The Secretariat is responsible to collect and assemble the data on substances selected for critical review. The Secretariat will use a questionnaire to request information from ministers of health in the Member States and international drug control bodies and will circulate the agenda of the next meeting.

22. The critical review document should be as thorough as possible, and balanced in its presentation. It should include the adequate and relevant data, including medical literature and abuse studies. In order to accomplish this, the Secretariat may seek assistance from advisers and ad hoc working groups.

23. When preparing the draft critical review document, including a separate report on the questionnaire, the Secretariat should include, where feasible, information under the following headings:

(1) substance identification by International Nonproprietary Name (INN), chemical or other common name and trade names, other identifying characteristics, Chemical Abstracts Service (CAS) registry number;

(2) chemistry, including general information on synthesis, preparation and properties;

(3) ease of convertibility into controlled substances;

(4) general pharmacology, including pharmacokinetics and pharmacodynamics;

(5) toxicology,

(6) adverse reactions in humans;

(7) dependence potential;

(8) abuse potential;

(9) therapeutic applications, extent of therapeutic use and epidemiology of medical use;

(10) listing on the WHO Model List of Essential Medicines;

(11) marketing authorizations (as a medicine);

(12) industrial use;

(13) non-medical use, abuse and dependence;

(14) nature and magnitude of public health problems related to abuse and dependence;

(15) licit production, consumption and international trade;

(16) illicit manufacture and traffic, and related information;

(17) current international controls and their impact;

(18) current and past national controls;

(19) other medical and scientific matters relevant for a recommendation on the scheduling of the substance.

24. The data in the critical review should be presented in a manner that will facilitate an evidence-based assessment by the Expert Committee. The critical review will comprise a summary and a section that compares the data directly against the scheduling criteria.

25. The draft critical review document and the report on the questionnaire are transmitted to all governments, institutions, organizations, or other interested parties that have directly and substantially collaborated in its preparation and have requested it. The recipients may provide comments on the

draft. To help to ensure that all material submitted to the Expert Committee is up to date, the Secretariat will circulate the agenda of the next meeting to those collaborating information sources.

26. For each substance, the draft critical review document and the report on the questionnaire will be peer-reviewed by two experts from WHO's Expert Advisory Panels, including an evaluation of the strength of evidence they present. If there are data limitations or omissions, they should be identified, discussed and adapted as needed.

27. The critical review document and the report on the questionnaire will be provided to all members of the Expert Committee at least thirty days before its meeting, and posted on the WHO web site, according to WHO rules for publication.

28. The confidentiality of information received by WHO for use in the review will be respected if so requested by the provider. Appropriate arrangements to sustain confidentiality will be made when the Expert Committee has access to the information used to prepare the pre-review and the critical review.

Preliminary review of exempted preparations containing psychotropic substances

29. The Secretariat should review the notification of exemption received from a Party to the 1971 Convention in order to ascertain whether the preparation containing a psychotropic substance is for domestic use only, or is being exported outside the exempting country. Where the preparation is for domestic use only, and if the exempting Party gives assurance in its notification that, to the best of its knowledge, there is no significant abuse, the Secretariat will assume that the exemption does not require an evaluation by the Expert Committee. However, if WHO receives evidence of national abuse, or information that the preparation may constitute a public health and social problem to another Party (e.g. illicit trade and/or abuse), the exemption shall be evaluated by the Expert Committee.

Expert Committee on Drug Dependence

30. In accordance with WHO's regulations, the Expert Committee meets when necessary to discuss the appropriate issues within its responsibility. As a guide, the Expert Committee should meet at least every second year.

31. **Membership.** The Expert Committee members are chosen by the Director-General in accordance with WHO's Regulations on Expert Advisory Panels and Committees. The Director-General shall establish the number of experts to be invited to a meeting of an Expert Committee on Drug Dependence, determine its date and duration, and convene the Expert Committee meeting.

32. **Functions.** The functions of the Expert Committee are to review information available to it on substances being considered for international control and for exemptions, and to advise the Director-General on such control. The advice of the Expert Committee concerns scientific, medical and public health findings and must comply with the criteria established in the Conventions. Specific responsibilities of the Expert Committee are:

(1) pre-review: to determine whether a substance should be subject to critical review;

(2) critical review: to assess the dependence-producing capability, the likelihood of abuse and of causing public health and social problems, and usefulness in medical therapy of each substance under review; and to advise on the appropriate schedule under one of the Conventions;

(3) exempted preparations: to evaluate the need to terminate notified exemptions of preparations under the 1971 Convention.

33. **Procedure.** WHO's Regulations on Expert Advisory Panels and Committees are applicable.

34. **Secretariat.** The Expert Committee is assisted by a secretariat, in particular by the Expert Committee's Secretary and furthermore by staff members from appropriate WHO programmes, consultants and temporary advisers, as required. The functions of the Secretary are executed by a technical officer competent in the subject concerned.

35. **Other organizations.** Representatives of United Nations organizations such as the United Nations Office on Drugs and Crime (UNODC), the International Narcotics Control Board (INCB), and appropriate nongovernmental organizations (NGOs) in official relations with WHO may be invited to attend the meetings of the Expert Committee as observers. In consultation with the members and the Secretariat, the Chair may decide to have a session of the Expert Committee with the members only.

36. The Expert Committee's recommendations and advice remain confidential until the clearing of their publication according to WHO's internal rules. All participants are required to respect the confidentiality of all information received as part of the Expert Committee process as well as the confidentiality of the Expert Committee's deliberations.

Information meeting

37. Interested parties that intend to make submissions of data may request the convening of an information meeting with the Expert Committee for this purpose. Requests for such a meeting should be submitted to the Secretariat at least twenty days before the start of the Expert Committee meeting. The request should state the nature and content of the presentation to be made at the meeting. All participants to the Expert Committee meeting are invited to this information meeting.

38. The purpose of the information meeting is to afford the Expert Committee the opportunity, before the Committee's meeting, to receive presentations and to question representatives of interested parties concerning data that have been provided about substances under review.

39. The information meeting will be held before the Expert Committee convenes its meeting. The Secretariat at its discretion shall decide the agenda of the information meeting, taking into account the nature of the proposed presentations and the time constraints for the meeting of the Expert Committee. The decisions of the Secretariat concerning the information meeting will be communicated to requesting interested parties at least 10 days before the Expert Committee meeting.

Experts collaborating in the WHO review

40. Experts collaborating in the review should have a well-documented scientific career at a high level and professional background, and should represent relevant behavioural, pharmacological, pharmaceutical, medical, biological, or epidemiological disciplines, as well as public health administration. Scientists representing industry research may be asked to collaborate as advisers in WHO ad hoc working groups, as appropriate, but they are not invited to participate in the Expert Committee meeting.

41. Experts participating in the WHO review should be selected with careful attention given to the avoidance of conflicts of interest. Similar considerations shall apply to all concerned with the process. In this connection, experts invited to participate in the WHO review and, in particular, in the work of the Expert Committee, sign a statement concerning potential conflicts of interest.

Assessment for scheduling by the Expert Committee

42. The Expert Committee bases its deliberations mainly on the documents provided by the Secretariat: these consist of the critical review document, the report on the questionnaire and comments received by the Secretariat concerning the critical review. The Expert Committee may also consider additional information presented in the information meeting. The information on which the critical review is based will be made available to the Expert Committee. The dissemination of this information may otherwise be restricted if needed to protect confidentiality requirements pursuant to paragraph 28.

43. Proposals for the change in control of a substance should be subjected to the same assessment that is given to substances proposed for initial scheduling; the same criteria as mentioned below in paragraphs 46 to 59 should be used in making the assessment.

44. To facilitate efficient administration of the international control system, it is not advisable to place a substance under more than one Convention. This is also true of substances that have been placed in a Table of the 1988 Convention, or have been recommended by INCB for inclusion in a Table.

45. A recommendation to delete a substance from one Convention with a simultaneous recommendation to add the same substance to another Convention may affect administration of the international scheme of regulation. Like all recommendations, consideration of such changes in control may be undertaken in light of new information to justify such a change. Any proposal to move a substance from one convention to another should be made only if specific new control measures are necessary in order to decrease the extent or likelihood of abuse or the use of the substance in illicit drug manufacturing, and will not unduly limit availability for legitimate medical and scientific purposes.

The assessment process

Orientation

46. Both the 1961 and 1971 Conventions provide for control of substances that are liable to "similar abuse and similar ill-effects" as substances already controlled under those Conventions. Many substances exhibit similarity in their "abuse" and "ill-effects" to substances in both the 1961 Convention and the 1971 Convention. Amphetamines, barbiturates and tranquillizers are only subject to the 1971 Convention, by virtue of an understanding of the Parties to the Conventions that the 1961 Convention did not apply to these substances even though the effects of amphetamines, barbiturates and tranquillizers were recognized to be similar to cocaine and morphine in some respects.[1] When considering other substances that exhibit abuse characteristics similar to substances regulated under both Conventions, the Expert Committee should follow the sequence for analysis established by the guidelines for all substances; that is, first consider applicability of the 1961 Convention and, if it is found not to apply, then the 1971 Convention. As such, the Committee would first assess whether the substance under review shows similar abuse liability profile (based on animal and human studies) and dependence-producing properties to drugs already controlled under the 1961 Convention. This assessment should not be limited to a narrow consideration of a single pharmacologic property. If the substance under review shows sufficiently similar abuse liability profile and dependence-producing properties to drugs already controlled under the 1961 Convention, then it should be recommended for scheduling under the 1961 Convention; if not, then the analysis should be made using the criteria in the 1971 Convention.

[1] Commentary on the 1961 Convention, Art.3, para.3, subpara (iii), Comment 6 (p.87).

47. The 1961 Convention provides for the control of substances convertible to narcotic drugs. The 1971 Convention provides for no such control of precursors. The 1988 Convention fills the void that existed for controlling precursors of psychotropic substances and the control of other chemicals frequently used in the illicit production of all controlled substances. INCB has responsibility for reviewing precursors of both narcotic and psychotropic substances for potential control. The Expert Committee might be asked to assess a substance to determine if it is convertible to a substance controlled under the 1961 Convention. If so, the Committee should determine if the substance is "convertible" as defined in paragraph 49 of these Guidelines, and then determine whether it is convertible to a substance controlled by the 1961 Convention.

Step 1: 1961 Convention

48. The Expert Committee, when deciding whether to recommend international control, or a change in international control, after completion of its discussions, first decides, with regard to the 1961 Convention, whether the substance in accordance with Article 3, paragraph 3 (iii) of that Convention: (1) is liable to similar abuse and productive of similar ill-effects as the substances in Schedule I or Schedule II; or (2) is convertible into a substance already in Schedule I or Schedule II.

49. In addition to the principle of "Similarity", laid down in Article 3, paragraph 3 (iii) of that Convention and mentioned in paragraph 48, the Convention also contains the principle of "Convertibility". A substance is convertible if it is of such a kind as to make it, by the ease of the process and by the yield, practicable and profitable for a clandestine manufacturer to transform the substance in question into controlled drugs.[1]

50. The Secretariat will promptly advise the INCB Secretariat of all Expert Committee assessments relating to substances that might be convertible into a narcotic drug. If the advice of the Expert Committee is to schedule a substance, whether psychoactive or convertible into a psychoactive substance, that is already in Table I or Table II of the 1988 Convention, the Secretariat will take steps to coordinate its proceedings with the INCB Secretariat. Such steps will enable INCB to review the possibility of recommending deletion of the substance from the Table of the 1988 Convention before WHO communicates its recommendation to the United Nations. If both WHO and INCB make such recommendations, CND could consider the two proposals simultaneously.

51. If a substance meets the criteria for inclusion in Schedule I of the 1961 Convention, the Expert Committee should further consider whether the drug meets the requirements for inclusion in Schedule IV in accordance with Article 3, paragraph 5 of that Convention, with regard to substances being particularly liable to abuse and to produce ill-effects and if such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV.

52. If the Expert Committee finds that a substance does not meet the criteria for control under the 1961 Convention, then it makes an assessment in accordance with the 1971 Convention.

[1] Commentary on the 1961 Convention, para. 13 (p.89).

Step 2: 1971 Convention

53. In considering the scheduling under the 1971 Convention, the Expert Committee determines whether, in accordance with Article 2, paragraph 4:

(a) The substance has the capacity to produce:

(i) (1) A state of dependence,[1] and

(2) Central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood, or

(ii) Similar abuse and similar ill-effects as a substance in Schedule I, II, III or IV, and

(b) There is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control.

54. In applying paragraph 53 of the Guidelines, the principle of similarity described in Article 2, paragraph 4(a)(ii) of the 1971 Convention applies only in situations when the substance does not produce a state of dependence. In the absence of a finding that a substance produces dependence, similarity takes on importance; otherwise it is secondary.

55. The Commentary on the 1971 Convention provides the following considerations to be taken into account in such an evaluation:

(i) "The assessment of the substance (…) should not only comprise the factual results of [WHO's] examination (…) *but also an evaluation of the data which it may have found in the light of such considerations of public health as it may consider appropriate* (...)" Commentary on the 1971 Convention, para. 41 (p. 58);

(ii) "WHO must also establish *the extent of abuse or the degree of likelihood of abuse* (…) in order to be able to determine whether [this] constitutes a public health and social problem warranting the placing of the substance under international control." Id., para. 42 (p. 58);

(iii) WHO must "assess *the degree of seriousness of the public health and social problem* (…). Since in arriving at its decision the [Commission on Narcotics Drugs will] weigh the dangerous properties of the substance against the non-medical considerations … it would find it useful to have the views of WHO on the degree of seriousness of the health and social problem which it has to take into account." Article 2, paragraph 5 … Id., para. 43 (p. 59);

(iv) WHO is required to include an assessment of *"the degree of usefulness of the substance in medical therapy* based on two considerations: (a) the degree of risk to public health and

[1] Dependence was defined by the 28th Expert Committee on Drug Dependence as: "A cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behaviour. Determinants and the problematic consequences of drug dependence may be biological, psychological or social, and usually interact." The Committee also mentioned that in its opinion this definition is compatible with the ICD-10 diagnostic guidelines. (WHO Expert Committee on Drug Dependence. Twenty-eighth report. Geneva, World Health Organization, 1993 (WHO Technical Report Series, No. 836)).

(b) the usefulness of the drug in medical therapy… [which means] not only its potential beneficial effects, its value in the case of grave medical indications and the extent and frequency of its employment, but also the intensity of its dangerous properties (…) and other harmful side effects may have to be taken into account." Id., para. 44 (pp. 59–60);

(v) It is safe to state that WHO in recommending a particular Schedule for a substance, "*will be guided by its views of the degree of risk to public health which the substance presents and its usefulness in medical therapy.*" Id., para. 49 (p. 61).

56. On the basis of the above considerations, more specific criteria for proposing to include a substance for control in a particular schedule were developed by the Expert Committee at its seventeenth meeting.[1] They are as follows:

For inclusion in Schedule I:

Substances whose liability to abuse constitutes an especially serious risk to public health and which have very limited, if any, therapeutic usefulness.

For inclusion in Schedule II:

Substances whose liability to abuse constitutes a substantial risk to public health and which have little to moderate therapeutic usefulness.

For inclusion in Schedule III:

Substances whose liability to abuse constitutes a substantial risk to public health and which have moderate to great therapeutic usefulness.

For inclusion in Schedule IV:

Substances whose liability to abuse constitutes a smaller but still significant risk to public health and which have a therapeutic usefulness from little to great.

In cases where the above criteria apply only in part, the scheduling recommendation should be made with a higher regard to the risk to that dimension of public health specific to abuse liability.

Notwithstanding the above, recommendations for inclusion in Schedule I should be made only when the above criteria are fully met, with respect to both therapeutic usefulness and the risk to public health.

57. The criteria given in the foregoing paragraph do not specifically address the dimension of social problems, although the Commentary on the 1971 Convention does. It is also noted that the above criteria do not cover all cases. The "risk to public health" in the above criteria should be interpreted to mean both social and public health problems. Note that under Article 2, paragraph 4(b) there must be a finding of an "international" need for control, meaning that controls of the Convention are suitable to solve or alleviate the problem and that lack of those controls in one country, no matter whether it has itself the public health and social problem caused by the substance under examination, weakens the control in other countries which have such a problem. International control is also warranted if the

[1] WHO Expert Committee on Drug Dependence. Seventeenth report. Geneva, World Health Organization, 1970 (WHO Technical Report Series, No. 437).

public health and social problem exists only in a single country if the efforts of control by that country are weakened by the lack of control in other countries.

58. If the advice of the Expert Committee is to include a substance that is already in Table I or Table II of the 1988 Convention, the WHO Secretariat will take steps to coordinate its proceedings with the INCB Secretariat. Such steps will enable INCB to review the possibility of recommending deletion of the substance from the Table of the 1988 Convention before WHO communicates its recommendation to the United Nations. If both WHO and INCB make such recommendations, CND could consider the two proposals simultaneously.

59. The Expert Committee shall provide its recommendation on the scheduling status on all drugs or substances under review as described in paragraph 60. Should the Expert Committee be unable to make a recommendation concerning substances under review, then it should request another critical review in order to refer the matter to a subsequent Expert Committee.[1]

Step 3: The report

60. The Expert Committee prepares a summary assessment of each substance reviewed. This assessment should include the Expert Committee's findings regarding pharmacological similarity, similar abuse, and similar ill-effects of the substance to substances in Schedules I and II of the 1961 Convention and, in the case of a "convertible" substance, an assessment of the convertibility of the substance into a substance already controlled as a narcotic drug. If the substance is recommended for control under the 1971 Convention, the assessment should also indicate whether the substance is being recommended for such control as a dependence-producing substance or on the basis of similarity. For all substances reviewed, the summary assessment should give a description of the Expert Committee's findings on the extent or likelihood of abuse, the degree of seriousness of the public health and social problem, and the degree of usefulness of the substance in medical therapy, together with the advice on the control measures, if any, that would be appropriate in the light of its assessment. The Expert Committee will advise the Director-General on its assessment and recommendation. The Expert Committee's report will be published and made available on the WHO web site in conformity with WHO rules for publication of Expert Committee reports.

Assessment of exempted preparations by the Expert Committee

61. The assessment of exempted preparations by the Expert Committee should evaluate the following elements: (1) conformity with the requirements of Article 3, paragraph 2, of the 1971 Convention concerning abuse liability and recoverability of the psychotropic substances as well as with CND resolution 1 (S-VIII); and (2) the evidence available to WHO that the preparation may constitute a public health and social problem to an importing country or to a country where it is illicitly traded. On conclusion of the assessment, the Expert Committee advises the Director-General accordingly.[2]

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[1] WHO Expert Committee on Drug Dependence. Thirty-fourth report. Geneva, World Health Organization, 2007 (WHO Technical Report Series, No. 942), pp. 17–18.

[2] See also Appendix 2.

V. COMMUNICATION OF WHO RECOMMENDATIONS

62. After receiving the advice of the Expert Committee to schedule or to amend the scheduling status of a substance, the Director-General will, as appropriate, communicate the recommendation on behalf of WHO to the United Nations. Copies of the recommendation are made available on the WHO web site concurrently.

63. Any recommendation to terminate an exemption in whole or in part will be communicated by the Director-General to the exempting Party if the abuse problem is limited to the country of origin of the preparation, or to the United Nations if the problems are widespread.

VI. PUBLICATION OF DOCUMENTS RELATED TO THE WHO REVIEW

64. The Director-General will submit to the Executive Board a report of the meetings of the ECDD in accordance with paragraph 4.23 of the Regulations on Expert Advisory Panels and Committees, and the report of the Expert Committee is published according to the WHO rules, both in the WHO Technical Report Series and on the WHO web site. The publication of any other document prepared for the Expert Committee is subject to Rule 4.15 of the Regulations for Expert Advisory Panels and Committees, which states that the Director-General may publish or authorize the publication of any document prepared for an expert committee, with due recognition of authorship if applicable.

VII. ABBREVIATIONS AND DEFINITIONS

CND	The Commission on Narcotic Drugs of the Economic and Social Council of the United Nations.
Expert Committee	In this document, “the Expert Committee” refers to the WHO Expert Committee on Drug Dependence. The First World Health Assembly decided in 1948, by resolution WHA1.25, to establish the Expert Committee on Habit-Forming Drugs which, since its sixteenth meeting (1968), is named Expert Committee on Drug Dependence.
INCB	The International Narcotics Control Board established by the Single Convention on Narcotic Drugs, 1961, and that Convention as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961.
Member State	A State which is a Member of WHO.
Narcotic drug	Any of the substances in Schedules I and II of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, whether natural or synthetic.
Notification	A formal communication addressed to the Secretary-General of the United Nations by a Party to an international drug control convention or by WHO, or by the Secretary-General of the United Nations to a Party to an international drug control convention or to WHO. In the context of the present guidelines, reference to a notification means a notification relating to the scheduling of a substance under the

	provisions of either Article 3 of the Single Convention or Articles 2 and 3 of the Convention on Psychotropic Substances.
Party	A State which has become a Party to an international drug control convention, through signature, ratification, accession, or succession.
Psychoactive substance	Any substance, natural or synthetic, or any natural substance material, which has psychoactive properties.
Psychotropic substance	Any substance, natural or synthetic, or any natural material in Schedule I, II, III or IV of the Convention on Psychotropic Substances, 1971.
Secretariat	The Secretariat of WHO.
The 1961 Convention	Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.
The 1971 Convention	Convention on Psychotropic Substances, 1971.
The 1988 Convention	United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.
UNODC	United Nations Office on Drugs and Crime.

APPENDIX 1

EXCERPTS FROM THE UNITED NATIONS DRUG CONTROL CONVENTIONS

Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (Extract)[1]

Article 3

CHANGES IN THE SCOPE OF CONTROL

1. Where a Party or the World Health Organization has information which in its opinion may require an amendment to any of the Schedules, it shall notify the Secretary-General and furnish him with the information in support of the notification.

2. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission, and, where the notification is made by a Party, to the World Health Organization.

3. Where a notification relates to a substance not already in Schedule I or in Schedule II,

i) The Parties shall examine in the light of the available information the possibility of the provisional application to the substance of all measures of control applicable to drugs in Schedule I;

ii) Pending its decision as provided in subparagraph iii) of this paragraph, the Commission may decide that the Parties apply provisionally to that substance all measures of control applicable to drugs in Schedule I. The Parties shall apply such measures provisionally to the substance in question;

iii) If the World Health Organization finds that the substance is liable to similar abuse and productive of similar ill-effects as the drugs in Schedule I or Schedule II or is convertible into a drug, it shall communicate that finding to the Commission which may, in accordance with the recommendation of the World Health Organization, decide that the substance shall be added to Schedule I or Schedule II.

4. If the World Health Organization finds that a preparation because of the substances which it contains is not liable to abuse and cannot produce ill-effects (paragraph 3) and that the drug therein is not readily recoverable, the Commission may, in accordance with the recommendation of the World Health Organization, add that preparation to Schedule III.

5. If the World Health Organization finds that a drug in Schedule I is particularly liable to abuse and to produce ill-effects (paragraph 3) and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV, the Commission may, in accordance with the recommendation of the World Health Organization, place that drug in Schedule IV.

[1] Single Convention on Narcotic Drugs, 1961. New York, United Nations, 1977, pp. 17–18.

6. Where a notification relates to a drug already in Schedule I or Schedule II or to a preparation in Schedule III, the Commission, apart from the measure provided for in paragraph 5, may, in accordance with the recommendation of the World Health Organization, amend any of the Schedules by:

a) Transferring a drug from Schedule I to Schedule II or from Schedule II to Schedule I;

or

b) Deleting a drug or a preparation as the case may be, from a Schedule.

7. Any decision of the Commission taken pursuant to this article shall be communicated by the Secretary-General to all States Members of the United Nations, to non-member States Parties to this Convention, to the World Health Organization and to the Board. Such decision shall become effective with respect to each Party on the date of its receipt of such communication, and the Parties shall thereupon take such action as may be required under this Convention.

8. a) The decisions of the Commission amending any of the Schedules shall be subject to review by the Council upon the request of any Party filed within ninety days from receipt of notification of the decision. The request for review shall be sent to the Secretary-General together with all relevant information upon which the request for review is based;

b) The Secretary-General shall transmit copies of the request for review and relevant information to the Commission, the World Health Organization and to all the Parties inviting them to submit comments within ninety days. All comments received shall be submitted to the Council for consideration;

c) The Council may confirm, alter or reverse the decision of the Commission, and the decision of the Council shall be final. Notification of the Council's decision shall be transmitted to all States Members of the United Nations, to non-member States Parties to this Convention, to the Commission, to the World Health Organization, and to the Board;

d) During pendency of the review the original decision of the Commission shall remain in effect.

9. Decisions of the Commission taken in accordance with this article shall not be subject to the review procedure provided for in article 7.

Convention on Psychotropic Substances, 1971 (Extracts)[1]

Article 2

SCOPE OF CONTROL OF SUBSTANCES

…

4. If the World Health Organization finds:

a) That the substance has the capacity to produce

i) 1) A state of dependence, and

2) Central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood, or

ii) Similar abuse and similar ill-effects as a substance in Schedule I, II, III or IV, and

b) That there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control, the World Health Organization shall communicate to the Commission an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy, together with recommendations on control measures, if any, that would be appropriate in the light of its assessment.

5. The Commission, taking into account the communication from the World Health Organization, whose assessments shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may add the substance to Schedule I, II, III or IV. The Commission may seek further information from the World Health Organization or from other appropriate sources.

…

Article 3

SPECIAL PROVISIONS REGARDING THE CONTROL OF PREPARATIONS

1. Except as provided in the following paragraphs of this article, a preparation is subject to the same measures of control as the psychotropic substance which it contains, and, if it contains more than one such substance, to the measures applicable to the most strictly controlled of those substances.

2. If a preparation containing a psychotropic substance other than a substance in Schedule I is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem, the preparation may be exempted from certain of the measures of control provided in this Convention in accordance with paragraph 3.

[1] Convention on Psychotropic Substances, 1971. New York, United Nations, 1977, pp. 9 and 12–13.

3. If a Party makes a finding under the preceding paragraph regarding a preparation, it may decide to exempt the preparation, in its country or in one of its regions, from any or all of the measures of control provided in this Convention except the requirements of:

a) article 8 (licences), as it applies to manufacture;

b) article 11 (records), as it applies to exempt preparations;

c) article 13 (prohibition of and restrictions on export and import);

d) article 15 (inspection), as it applies to manufacture;

e) article 16 (reports to be furnished by the Parties), as it applies to exempt preparations; and

f) article 22 (penal provisions), to the extent necessary for the repression of acts contrary to laws or regulations adopted pursuant to the foregoing obligations.

A Party shall notify the Secretary-General of any such decision, of the name and composition of the exempt preparation, and of the measures of control from which it is exempted. The Secretary-General shall transmit the notification to the other Parties, to the World Health Organization and to the Board.

4. If a Party or the World Health Organization has information regarding a preparation exempted pursuant to paragraph 3 which in its opinion may require the termination, in whole or in part, of the exemption, it shall notify the Secretary-General and furnish him with the information in support of the notification. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission and, when the notification is made by a Party, to the World Health Organization. The World Health Organization shall communicate to the Commission an assessment of the preparation in relation to the matters specified in paragraph 2, together with a recommendation of the control measures, if any, from which the preparation should cease to be exempted. The Commission, taking into account the communication from the World Health Organization, whose assessment shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may decide to terminate the exemption of the preparation from any or all control measures. Any decision of the Commission taken pursuant to this paragraph shall be communicated by the Secretary-General to all States Members of the United Nations, to non-member States Parties to this Convention, to the World Health Organization and to the Board. All Parties shall take measures to terminate the exemption from the control measure or measures in question within 180 days of the date of the Secretary-General's communication.

United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (Extracts)[1]

Article 12

SUBSTANCES FREQUENTLY USED IN THE ILLICIT MANUFACTURE OF NARCOTIC DRUGS OR PSYCHOTROPIC SUBSTANCES

1. The Parties shall take the measures they deem appropriate to prevent diversion of substances in Table I and Table II used for the purpose of illicit manufacture of narcotic drugs or psychotropic substances, and shall co-operate with one another to this end.

2. If a Party or the Board has information which in its opinion may require the inclusion of a substance in Table I or Table II, it shall notify the Secretary-General and furnish him with the information in support of that notification. The procedure described in paragraphs 2 to 7 of this article shall also apply when a Party or the Board has information justifying the deletion of a substance from Table I or Table II, or the transfer of a substance from one Table to the other.

3. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission, and, where notification is made by a Party, to the Board. The Parties shall communicate their comments concerning the notification to the Secretary-General, together with all supplementary information which may assist the Board in establishing an assessment and the Commission in reaching a decision.

4. If the Board, taking into account the extent, importance and diversity of the licit use of the substance, and the possibility and ease of using alternate substances both for licit purposes and for the illicit manufacture of narcotic drugs or psychotropic substances, finds:

a) That the substance is frequently used in the illicit manufacture of a narcotic drug or psychotropic substance;

b) That the volume and extent of the illicit manufacture of a narcotic drug or psychotropic substance creates serious public health or social problems, so as to warrant international action,

it shall communicate to the Commission an assessment of the substance, including the likely effect of adding the substance to either Table I or Table II on both licit use and illicit manufacture, together with recommendations of monitoring measures, if any, that would be appropriate in the light of its assessment.

5. The Commission, taking into account the comments submitted by the Parties and the comments and recommendations of the Board, whose assessment shall be determinative as to scientific matters, and also taking into due consideration any other relevant factors, may decide by a two-thirds majority of its members to place a substance in Table I or Table II.

…

[1] United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

APPENDIX 2

RESOLUTION 1 (S-VIII) OF THE UNITED NATIONS COMMISSION ON NARCOTIC DRUGS[1]

Guidelines for the exemption of preparations from certain control measures under the provisions of Article 3 of the 1971 Convention on Psychotropic Substances

The Commission on Narcotic Drugs,

Having taken note of documents MNH/78.1 and MNH/82.51 containing proposals by World Health Organization consultative groups concerning guidelines for granting exemptions under the provisions of article 3 of the 1971 Convention on Psychotropic Substances,

Having considered the report by the Secretary-General of 16 December 1983 entitled Review of establishment of guidelines for the exemption of preparations under the provisions of article 3 of the 1971 Convention on Psychotropic Substances (E/CN.7/1984/4),

Recalling its resolutions 2 (S-VI) of 19 February 1980 and 5 (XXX) of 16 February 1983,

Bearing in mind that decisions taken by it in respect of the termination of an exemption must consider the social and economic conditions pertaining in the country granting the exemption, including the level of development of its national medical services and national drug distribution system,

Convinced of the need for Governments to contribute to the development of further guidelines, in light of the experience gained during the application of the guidelines currently in force,

Approves the following guidelines for use by national authorities, the World Health Organization and the Commission on Narcotic Drugs:

Guidelines proposed for use by national authorities

(a) A preparation containing a psychotropic substance in association with (i) another psychotropic substance, (ii) a narcotic drug or (iii) a psychoactive substance not under international control with known abuse potential, should not be exempted; nevertheless, exemption of a preparation in any of the three above categories which is compounded in such a manner that it presents a negligible risk of abuse may be envisaged;

(b) A preparation containing a psychotropic substance in association with a narcotic drug listed in Schedule I or II of the Single Convention on Narcotic Drugs, 1961, should not be exempted; exemption can only be authorized if the preparation has been listed in Schedule III of that Convention by the Commission, in accordance with the amendment procedure established by the provisions of article 3, paragraph 4, of the Convention;

c) A preparation containing a psychotropic substance in injectable dosage form should not be exempted;

[1] Extract from United Nations document E/CN.7/1984/13 (1984).

d) A preparation containing a psychotropic substance should not be exempted from the provisions of article 10, paragraph 1, of the 1971 Convention on Psychotropic Substances;

e) A preparation containing a psychotropic substance should not be exempted from the provisions of article 10, paragraph 2, of the 1971 Convention on Psychotropic Substances, unless such exemption would be in keeping with national statutory requirements;

f) A preparation containing a psychotropic substance should not be exempted from the requirements of article 12 of the 1971 Convention on Psychotropic Substances;

g) Guidelines (d), (e), and (f) notwithstanding, in vitro diagnostic reagents, buffers and analytical standards containing psychotropic substances may be exempted from the provisions of articles 10 and 12 of the 1971 Convention.

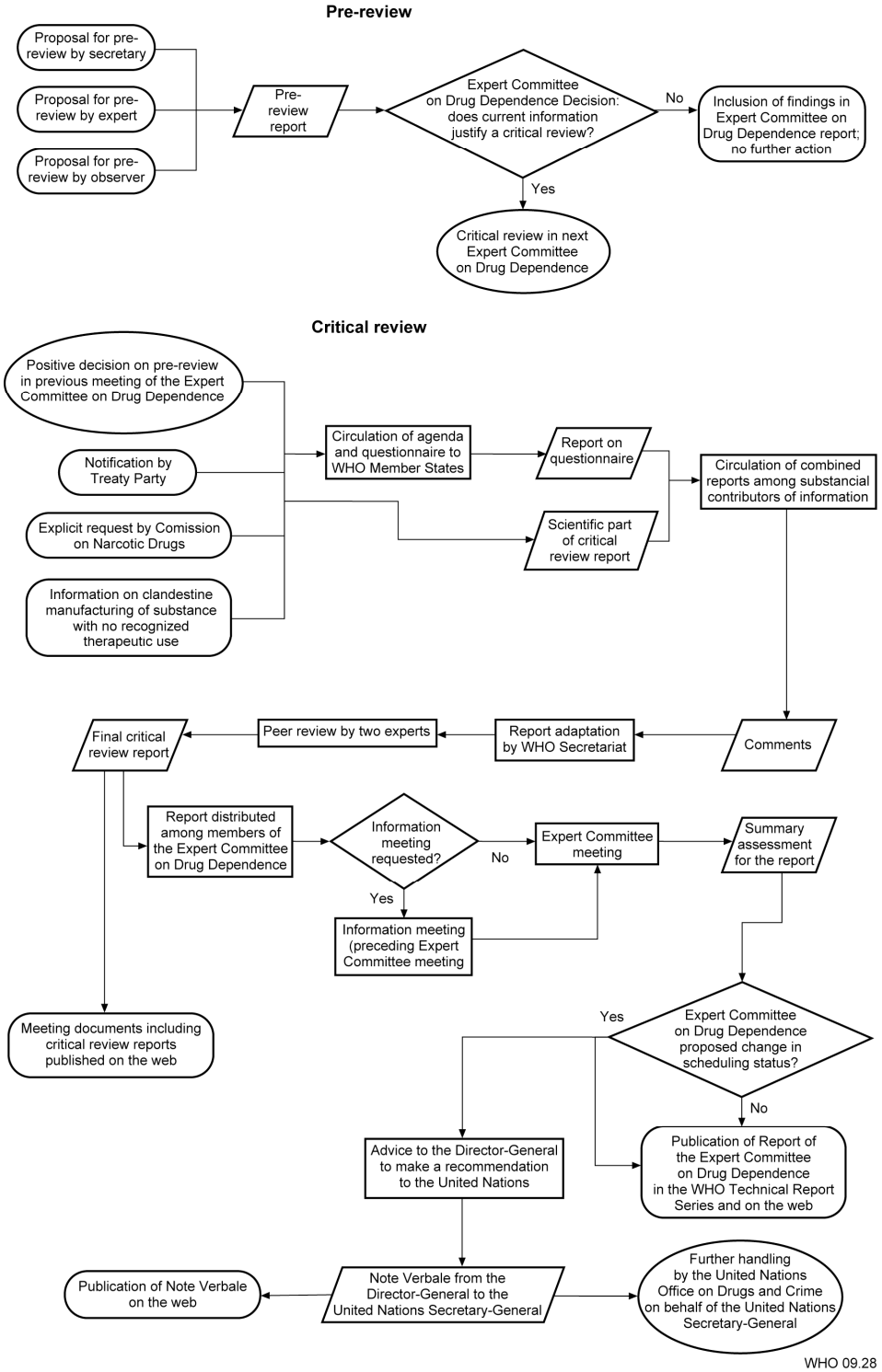
Guidelines proposed for use by the World Health Organization

h) The World Health Organization should not routinely review Parties' notifications of exemptions intended only for domestic use; however, where there is evidence that a specific exemption granted by a competent national authority does not comply with guidelines (a)–(e) above, and might constitute a danger to the public health of the country concerned, the World Health Organization should immediately draw the attention of the competent national authority to the possible public health hazard and advise the Commission on Narcotic Drugs of its action in this regard. If however, there is evidence that such exemption constitutes a danger to another country, the World Health Organization should proceed to examine the exemption as a matter of urgency.

APPENDIX 3

FLOW CHART OF THE EVALUATION PROCEDURE

WHO review of psychoactive substances for international control



ANNEX 7

Financial and administrative implications for the Secretariat of resolutions adopted by the Executive Board

1. Resolution EB126.R4 Monitoring of the achievement of the health-related Millennium Development Goals

2. Linkage to programme budget

Strategic objective:	Organization-wide expected results:
2. To combat HIV/AIDS, tuberculosis and malaria.	All expected results for this strategic objective.
4. To reduce morbidity and mortality and improve health during key stages of life, including pregnancy, childbirth, the neonatal period, childhood and adolescence, and improve sexual and reproductive health and promote active and healthy ageing for all individuals.	All expected results except 4.8.
10. To improve health services through better governance, financing, staffing and management, informed by reliable and accessible evidence and research.	All expected results except 10.6, 10.7 and 10.9.

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

The resolution is particularly relevant to strategic objective 10, which concerns both improved management and organization of health service delivery through a primary health-care approach, and enhanced monitoring and evaluation of progress. The resolution is also highly relevant to all strategic objectives concerned with the achievement of specific health outcomes, especially strategic objectives 1–4. Of the latter group, it particularly concerns strategic objective 2 and strategic objective 4. Other strategic objectives with relevance to the resolution include strategic objective 5 on emergencies and crises (expected results 5.1–5.3), strategic objective 6 on reducing risk factors for health conditions linked to unhealthy lifestyles (expected result 6.6), strategic objective 7 on tackling social and economic determinants of health and enhancing health equity (expected result 7.3), strategic objective 8 on promoting healthy environments (expected results 8.1–8.2), strategic objective 9 on nutrition and food safety and security (expected results 9.1–9.4), strategic objective 11 on ensuring access to medical products and technologies (expected results 11.1–11.3) and strategic objective 12 on leadership, partnerships and collaboration with countries (expected results 12.1–12.3).

3. Budgetary implications

(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US$ 10 000, including staff and activities)

The two major streams of work and associated costs relate to: (i) the production of the annual report on the health-related Millennium Development Goals; and (ii) the provision of technical support to countries for enhanced programme implementation, monitoring and evaluation. The former is primarily carried out at headquarters, the latter through the regional offices.

Total production costs for the annual report (as part of the publication, *World health statistics*): US$ 350 000.

Staff costs: 33% full-time equivalent, grade P6; 40% full-time equivalent, grade P5; 50% full-time equivalent, grade P4; and 50% full-time equivalent, grade P3. Total: US$ 1.9 million.

Total costs for regional office inputs: US$ 2 million.

Total costs: US$ 4 250 000.

(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant)

Total costs for implementation: US$ 1.7 million (US$ 900 000 at headquarters level and US$ 800 000 at regional office level).

(c) Is the estimated cost noted in (b), included within the existing approved Programme budget for the biennium 2010–2011?

Yes.

4. Financial implications

How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?

Headquarters: 50% from assessed contributions, 50% from voluntary contributions.

Regional offices: 100% from voluntary contributions.

5. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)

Implementation activities in respect of the annual report on the health-related Millennium Development Goals will take place at headquarters. Collaboration with all regional offices to enable improved availability of up-to-date information and support to countries for data analysis, reconciliation and estimation will be organized as needed.

(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below

Headquarters: yes, providing that funding continues to be available.

Regional offices: no for the Regional Office for Africa and the Regional Office for South-East Asia.

(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)

The Regional Office for Africa and the Regional Office for South-East Asia will need one staff member (full-time equivalent) to work with countries.

(d) Time frames (indicate broad time frames for implementation of activities)

From 2010 to 2015.

1. Resolution EB126.R5 Infant and young child nutrition: quadrennial progress report

2. Linkage to programme budget

Strategic objective:	Organization-wide expected result:
2. To combat HIV/AIDS, tuberculosis and malaria.	2.1 Guidelines, policy, strategy and other tools developed for prevention of, and treatment and care for patients with, HIV/AIDS, tuberculosis and malaria, including innovative approaches for increasing coverage of the interventions among poor people, and hard-to-reach and vulnerable populations. 2.2 Policy and technical support provided to countries towards expanded gender-sensitive delivery of prevention, treatment and care interventions for HIV/AIDS, tuberculosis and malaria, including

	integrated training and service delivery; wider service-provider networks; and strengthened laboratory capacities and better linkages with other health services, such as those for sexual and reproductive health, maternal, newborn and child health, sexually transmitted infections, nutrition, drug-dependence treatment services, respiratory care, neglected diseases and environmental health.
	2.4 Global, regional and national systems for surveillance, evaluation and monitoring strengthened and expanded to keep track of progress towards targets and allocation of resources for HIV/AIDS, tuberculosis and malaria control and to determine the impact of control efforts and the evolution of drug resistance.
4. To reduce morbidity and mortality and improve health during key stages of life, including pregnancy, childbirth, the neonatal period, childhood and adolescence, and improve sexual and reproductive health and promote active and healthy ageing for all individuals.	4.4 Guidelines, approaches and tools for improving neonatal survival and health applied at country level, with technical support provided to Member States for intensified action towards universal coverage, effective interventions and monitoring of progress.
	4.5 Guidelines, approaches and tools for improving child health and development applied at the country level, with technical support provided to Member States for intensified action towards universal coverage of the population with effective interventions and for monitoring progress, taking into consideration international and human-rights norms and standards, notably those stipulated in the Convention on the Rights of the Child.
7. To address the underlying social and economic determinants of health through policies and programmes that enhance health equity and integrate pro-poor, gender-responsive, and human rights-based approaches.	7.2 Initiative taken by WHO in providing opportunities and means for intersectoral collaboration at national and international levels to address social and economic determinants of health, including understanding and acting upon the public health implications of trade and trade agreements, and to encourage poverty reduction and sustainable development.
9. To improve nutrition, food safety and food security, throughout the life-course, and in support of public health and sustainable development.	9.1 Partnerships and alliances formed, leadership built and coordination and networking developed with all stakeholders at country, regional and global levels, in order to promote advocacy and communication, stimulate intersectoral actions, increase investment in nutrition, food-safety and food-security interventions, and develop and support a research agenda.
	9.2 Norms, including references, requirements, research priorities, guidelines, training manuals and standards, produced and disseminated to Member States in order to increase their capacity to assess and respond to all forms of malnutrition, and zoonotic and non-zoonotic foodborne diseases, and to promote healthy dietary practices.
	9.3 Monitoring and surveillance of needs and assessment and evaluation of responses in the area of nutrition and diet-related chronic diseases strengthened, and ability to identify best policy options improved, in stable and emergency situations.

9.4 Capacity built and support provided to target Member States for the development, strengthening and implementation of nutrition plans, policies and programmes aimed at improving nutrition throughout the life-course, in stable and emergency situations.

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

- Guidelines on nutrition interventions to be reviewed and developed, scaling up from 10 to 40 guidelines.
- Monitoring child growth, infant and young child feeding practices, micronutrient status and implementation of nutrition interventions performed, scaling up from 50 to 70 countries implementing growth standards; 5 micronutrient surveys implemented; and implementation data collected in 150 countries.
- Interagency collaborative initiatives developed at global and country levels in order to scale up nutrition programmes: 5 initiatives.
- Technical support for scaling up nutrition interventions provided to 20 countries and capacity building provided to an additional 15 countries.
- Technical support provided to Member States in strengthening and implementing national nutrition policies and strategies to scale up action in tackling the double burden of malnutrition: an additional 15 countries provided with support.
- Technical guidance provided on priority nutrition actions aimed at the prevention of tuberculosis and support against HIV: an additional 15 countries provided with support.

3. Budgetary implications

(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US$ 10 000, including staff and activities)

US$ 12 million (staff: US$ 5 million, activities: US$ 7 million) for three years.

(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant)

US$ 8.5 million (staff: US$ 4 million, activities: US$ 4.5 million; breakdown across the Organization: headquarters – US$ 2.5 million, regions – US$ 6 million).

(c) Is the estimated cost noted in (b), included within the existing approved Programme budget for the biennium 2010–2011?

Yes.

4. Financial implications

How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?

A global resource mobilization plan is being prepared to approach potential donors. Partial funding has been provided by the Governments of Italy, Japan, Luxembourg, Spain and United States of America and philanthropic bodies.

5. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)

Although the normative work (including guidelines development and scientific reviews) will be carried out at headquarters, the majority of activities will be undertaken at country and regional levels. Priority will be given to the 36 countries identified by WHO upon which malnutrition places the highest burden of mortality and morbidity.

(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below

As already recommended in the review conducted of WHO's nutrition work, staffing needs to be strengthened. This is particularly the case at country level and in some of the regional offices.

(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)

Staffing needs to be strengthened in all regions, particularly in African, South-East Asia and Eastern Mediterranean Regions. There is a particular need for technical nutrition staff at the P.2 and P.3 levels.

(d) Time frames (indicate broad time frames for implementation of activities)

Implementation of some activities under this resolution has already started in the current biennium. Most activities will be implemented by the first quarter of 2011.

1. Resolution EB126.R7 Advancing food safety initiatives

2. Linkage to programme budget

Strategic objective:	Organization-wide expected result:
1. To reduce the health, social and economic burden of communicable diseases.	1.3. Effective coordination and support provided to Member States in order to provide access for all populations to interventions for the prevention, control, elimination and eradication of neglected tropical diseases, including zoonotic diseases.
5. To reduce the health consequences of emergencies, disasters, crises and conflicts, and minimize their social and economic impact.	5.5. Support provided to Member States for strengthening national preparedness and for establishing alert and response mechanisms for food-safety and environmental health emergencies.
9. To improve nutrition, food safety and food security, throughout the life-course, and in support of public health and sustainable development.	9.1. Partnerships and alliances formed, leadership built and coordination and networking developed with all stakeholders at country, regional and global levels, in order to promote advocacy and communication, stimulate intersectoral actions, increase investment in nutrition, food-safety and food-security interventions, and develop and support a research agenda.
	9.2. Norms, including references, requirements, research priorities, guidelines, training manuals and standards, produced and disseminated to Member States in order to increase their capacity to assess and respond to all forms of malnutrition, and zoonotic and non-zoonotic foodborne diseases, and to promote healthy dietary practices.

9.5. Systems for surveillance, prevention and control of zoonotic and non-zoonotic foodborne diseases strengthened; food-hazard monitoring and evaluation programmes established and integrated into existing national surveillance systems, and results disseminated to all key players.

9.6. Capacity built and support provided to Member States, including their participation in international standard-setting in order to increase their ability to assess risk in the areas of zoonotic and non-zoonotic foodborne diseases and food safety, and to develop and implement national food-control systems, with links to international emergency systems.

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

The resolution will provide an updated framework for WHO's normative work on food safety within the existing expected results, with an additional emphasis on strengthening scientific advice, the estimation of the health burden imposed by foodborne disease, support for the International Food Safety Authorities Network (INFOSAN) and cross-sectoral prevention of zoonotic diseases.

3. Budgetary implications

(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US$ 10 000, including staff and activities):

US$ 29.1 million over the coming six-year period (staff: US$ 16.5 million, activities: US$ 12.6 million).

(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant):

US$ 9.7 million at headquarters.

(c) Is the estimated cost noted in (b) included within the existing approved Programme budget for the biennium 2010–2011?

US$ 8 million are included in the Programme budget.

4. Financial implications

How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?

Through the extrabudgetary funds of interested Member States and relevant nongovernmental organizations.

5. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)

Implementation will be organized at headquarters, in coordination with all six regional offices and selected countries of each region.

(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below

No.

(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)

Two staff members in the professional category at headquarters.

(d) Time frames (indicate broad time frames for implementation of activities)

Food safety initiatives are continuing activities. The next progress report will be made to the Sixty-fifth World Health Assembly; thus the major new initiatives should be evaluated by the end of the period 2010–2011.

1. Resolution EB126.R12 The improvement of health through safe and environmentally sound waste management

2. Linkage to programme budget

Strategic objective:	Organization-wide expected result:
8. To promote a healthier environment, intensify primary prevention and influence public policies in all sectors so as to address the root causes of environmental threats to health.	8.2 Technical support and guidance provided to Member States for the implementation of primary prevention interventions that reduce environmental hazards to health, enhance safety and promote public health, including in specific settings (e.g. workplaces, homes or urban settings) and among vulnerable population groups (e.g. children).

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

The resolution is consistent with the expected result and implementation would facilitate achievement of the target for 2011 of 12 Member States implementing primary prevention interventions in order to reduce environmental risks to health, with WHO technical support, in at least one of the following settings: workplaces, homes or urban settings. The baseline figure for 2010 will remain the same as for 2009 (namely 8).

3. Budgetary implications

(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US$ 10 000, including staff and activities)

No additional costs will be incurred regarding activities. The resolution requests the Secretariat to support the implementation of the actions set out in the Bali Declaration, within the Organization's mandate and available resources. The workplan for the biennium 2010–2011 already includes activities aimed at responding to the problem of hazardous waste, in particular health care waste, in conjunction with other relevant bodies including UNEP and the Basel Convention secretariat.

(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant)

No additional costs are envisaged specifically under the resolution.

(c) Is the estimated cost noted in (b), included within the existing approved Programme budget for the biennium 2010–2011?

Not applicable.

4. Financial implications

How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?

Not applicable.

5. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)

Primary prevention activities will mainly be conducted at country level; multicountry projects will be undertaken through headquarters and the regional offices; and liaison with UNEP and the Basel Convention will mainly be managed through headquarters and the regional offices.

(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below

Yes.

(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)

Not applicable.

(d) Time frames (indicate broad time frames for implementation of activities)

There will be a continuing need to tackle the problem of health-care and other hazardous waste to ensure that waste generation is minimized on a lasting basis. Therefore, the initial time frame under this resolution will follow the Medium-term strategic plan until 2013. Thereafter, it will be reviewed as necessary.

1. Resolution EB126.R13 Improvement of health through sound management of obsolete pesticides and other obsolete chemicals

2. Linkage to programme budget

Strategic objective:	Organization-wide expected result:
8. To promote a healthier environment, intensify primary prevention and influence public policies in all sectors so as to address the root causes of environmental threats to health.	8.1 Evidence-based assessments made, and norms and standards formulated and updated on major environmental hazards to health (e.g. poor air quality, chemical substances, electromagnetic fields, radon, poor-quality drinking-water and waste-water reuse). 8.2 Technical support and guidance provided to Member States for the implementation of primary prevention interventions that reduce environmental hazards to health, enhance safety and promote public health, including in specific settings (e.g. workplaces, homes or urban settings) and among vulnerable population group (e.g. children). 8.3 Technical assistance and support provided to Member States for strengthening national occupational and environmental health risk management systems, functions and services. 8.5 Health-sector leadership enhanced for creating a healthier environment and changing policies in all sectors so as to tackle the root causes of environmental threats to health, through means such as responding to emerging and re-emerging consequences of

development on environmental health and altered patterns of consumption and production and to the damaging effect of evolving technologies.

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

The resolution is consistent with the listed expected results and supports indicators relating to: Member States assessing environmental threats to health, implementing primary prevention of environmental risks to health and implementing national action plans or policies for the management of occupational health. The baselines remain the same.

3. Budgetary implications

(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US$ 10 000, including staff and activities)

The timeline is not specified and implementation of the resolution is expected to continue over time since additional pesticides and chemicals are likely to be rendered obsolete by risk management actions. The Secretariat's planned activities are largely directed towards specific substances of concern, such as phasing out the use of lead, mercury and asbestos. The current level of activity at headquarters on such substances entails a cost of some US$ 500 000 per biennium. Implementation of comprehensive activities on obsolete pesticides and obsolete chemicals in general is estimated to require an additional cost of approximately the same amount.

(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant)

See section 3(a) above.

(c) Is the estimated cost noted in (b) included within the existing approved Programme budget for the biennium 2010–2011?

The current level of activity on specific substances of concern, estimated at US$ 500 000, is included within the existing Programme budget.

4. Financial implications

How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?

Voluntary contributions from interested Member States and relevant nongovernmental resources.

5. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)

Headquarters (coordination of implementation and provision of general guidance to regional and country offices) and regional offices in consultation with countries.

(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below

The current level of activity can be sustained by existing staff. Implementation of comprehensive activities on obsolete pesticides and obsolete chemicals in general will require additional staff (see (c) below).

(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)

Comprehensive activities will require an additional staff member in the professional category (25% full-time equivalent).

(d) Time frames (indicate broad time frames for implementation of activities)

The timeline is not specified and implementation is expected to continue over time (see 3(a) above).

1. Resolution EB126.R15 Accelerating progress towards achievement of Millennium Development Goal 4 to reduce child mortality: prevention and treatment of pneumonia

2. Linkage to programme budget

Strategic objective:	Organization-wide expected result:
1. To reduce the health, social and economic burden of communicable diseases.	1.1 Policy and technical support provided to Member States in order to maximize equitable access of all people to vaccines of assured quality, including new immunization products and technologies, and to integrate other essential child-health interventions with immunization.
4. To reduce morbidity and mortality and improve health during key stages of life, including pregnancy, childbirth, the neonatal period, childhood and adolescence, and improve sexual and reproductive health and promote active and healthy ageing for all individuals.	4.5 Guidelines, approaches and tools for improving child health and development applied at the country level, with technical support provided to Member States for intensified action towards universal coverage of the population with effective interventions and for monitoring progress, taking into consideration international and human-rights norms and standards, notably those stipulated in the Convention on the Rights of the Child.

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

The resolution is consistent with the listed expected results and supports the following indicators: for strategic objective 1 – (i) number of Member States with at least 90% immunization coverage (DPT 3); and (ii) number of Member States that have introduced *Haemophilus influenzae* type b vaccine into their national immunization schedule; and for strategic objective 4 – (i) number of targeted Member States that have an integrated policy on universal access to effective interventions for improving maternal, newborn and child health and (ii) number of Member States implementing strategies for increasing coverage with child health and development interventions.

3. Budgetary implications

(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US$ 10 000, including staff and activities)

US$ 110 million are required for the period 2010–2015 in respect of costs at headquarters and at regional and country office levels.

(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant)

In respect of strategic objective 1: headquarters – total US$ 5.9 million (US$ 900 000 for staff, US$ 5 million for activities); regional and country offices – total US$ 27.4 million (US$ 5 million for staff, US$ 22.4 million for activities).

In respect of strategic objective 4: headquarters – total US$ 600 000 (US$ 450 000 for staff, US$ 150 000 for activities); regional and country offices – total US$ 8 million (US$ 2.4 million for staff, US$ 5.6 million for activities).

(c) Is the estimated cost noted in (b), included within the existing approved Programme budget for the biennium 2010–2011?

Yes.

4. Financial implications

How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?

In respect of strategic objective 1: funds for 2010 are available through the GAVI Alliance and the Gates Foundation. Some of the funding required for 2011 may be available through the same sources, but a funding gap is likely to appear in 2011.

In respect of strategic objective 4: voluntary contributions will be sought to fund these activities.

5. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)

All levels of WHO, with a specific focus on the 68 priority countries that are the focus of the "Countdown to 2015" initiative, on which the disease places a high burden. Most of the countries concerned are also eligible for funding from the GAVI Alliance.

(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below

No. Additional staff will be needed to implement the resolution, especially in countries with a high burden of the disease.

(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)

Three staff members (full-time equivalent) at the P4 grade: 1 at headquarters, 1 at the Regional Office for South-East Asia and 1 at country level.

(d) Time frames (indicate broad time frames for implementation of activities)

The period 2010–2015.

1. Resolution EB126.16 Viral hepatitis

2. Linkage to programme budget

Strategic objective:	Organization-wide expected result:
1. To reduce the health, social and economic burden of communicable diseases.	1.1 Policy and technical support provided to Member States in order to maximize equitable access of all people to vaccines of assured quality, including new immunization products and technologies, and to integrate other essential child-health interventions with immunization. 1.4 Policy and technical support provided to Member States in order to enhance their capacity to carry out surveillance and monitoring of all communicable diseases of public health importance. 1.5 New knowledge, intervention tools and strategies that meet priority needs for the prevention and control of communicable diseases developed and validated, with scientists from developing countries increasingly taking the lead in this research.

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

The resolution is consistent with the expected result. Indicators specific to prevention of viral hepatitis will be designed as needed.

3. Budgetary implications

(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US$ 10 000, including staff and activities)

US$ 30 million are needed for the next five years. Of this amount, one third (US$ 10 million) is needed at headquarters for global planning and coordination between stakeholders, global policy guidance, and the provision of support to regional and country offices; two thirds (US$ 20 million) are needed for support activities at regional and country levels.

(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant)

Total costs are estimated at US$ 6 million per year.

(c) Is the estimated cost noted in (b) included within the existing approved Programme budget for the biennium 2010–2011?

The Organization's hepatitis prevention activities involve a number of technical units. It is difficult to know the true amount of resources available for these activities as they may not be directly identified in the Programme budget and may, for example, be covered under references to blood safety, injection safety, food safety, cancer prevention, child immunization or treatment of opportunistic infections in HIV/AIDS.

4. Financial implications

How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?

Additional funding from voluntary contributions is expected through active resource mobilization.

5. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)

Currently, most activities are performed at headquarters (policy and technical guidance, global advocacy and stakeholder coordination, and fund-raising) and in two WHO regions (Eastern Mediterranean and Western Pacific).

(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below

No.

(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)

At headquarters, at least two additional staff (full-time equivalents) will be required in the professional category, together with one staff member (full-time equivalent) in the general service category. During the biennium 2010–2011, one additional staff member (full-time equivalent) will be needed in the professional category in each of three regional offices (plus administrative support); during the biennium 2012–2013, three more staff (full-time equivalents) will be needed for the other regional offices (plus administrative support). A total of eight staff (full-time equivalents) will therefore be required in the professional category, together with three or four staff (full-time equivalents) in the general service category. In at least 10 countries, a dedicated national programme officer will be needed.

(d) Time frames (indicate broad time frames for implementation of activities)

The global programme will be expanded into the African, European, and Eastern Mediterranean regions in 2010, and into all regions during the biennium 2010–2011.

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